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THE MICROBIAL SAFETY OF FRESH PRODUCE
PUBLIC MEETING

MAY 21, 1998

2320 '98 JUN 18 P12:2

Taken before Pearlyck Valiente, Notary Public in
and for the State of Florida at Large, 10:00 a.m., on
Thursday, May 21, 1998, and concluding at 5:15 p.m., at the
Metro-Dade County Cooperative Extension Service Agriculture
Center, 18710 S.W. 288th Street, Homestead, Florida 33033,
pursuant to Notice of Hearing in the above-styled cause.

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97N-0451

TR10

1 APPEARANCES:

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3 Moderator, Estela Niella-Brown, FDA Public Affairs
4 Specialist.

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6 Lou Carson, FDA, Deputy Director of the Food Safety
7 Initiative.

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9 Douglas Tolen, FDA, District Director, Florida District.

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11 Martha R. Roberts, Florida State Department of
12 Agriculture and Consumer Services, Deputy Commissioner for
13 Food Safety.

14

15 Donald W. Pybas, Director, Miami-Dade County Extension
16 Service.

17

18 H. Wayne Derstine, Florida State Department of
19 Agriculture and Consumer Services, Environmental
20 Administrator, Food Inspector.

21

22 Ricardo Gomes, USDA, Chief Horticulturalist, Cooperative
23 State Research Education and Extension Service.

24

25 Foreign Technical Cooperation, Lloyd Harbert, USDA,

1 Director, Food Safety and Technical Division, Foreign
2 Agriculture Service.

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4 Michelle Smith, Interdisciplinay Scientist, FDA.

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1 MS. NIELLA-BROWN: Good morning, my name is
2 Estela Niella-Brown and I am a public affairs
3 specialist for the U.S. Food and Drug
4 Administration, Miami office. And I would like to
5 welcome you to this public meeting on the microbial
6 safety of fresh produce.

7 Each of you should have registered outside.
8 If anybody has not registered yet, please do. And
9 at the registration table you will find an
10 information package such as this, the Fight-Bac,
11 keep food safe from bacteria. And by the way, Bac
12 is the new character for the Food Safety
13 Initiative. I just wanted to introduce him or her
14 to you if you still had not had the pleasure of
15 meeting Bac.

16 In your package you would also have a
17 document, which is guidance for industry. That's
18 the draft guide that we will be covering today, and
19 you also will have an executive summary and a copy
20 of the Federal Register announcement for this
21 meeting.

22 I would like you to keep in mind that the most
23 important aspect of this meeting is the exchange.
24 We would like to keep the meeting as informal as
25 possible, and the most important objective of all

1 of us being here is to gather input from all
2 segments of the community interested in this topic.
3 So in the Federal Register announcement there is an
4 address to which you could send comments if you
5 think of something that you didn't think of during
6 this meeting. When you get home, if you think
7 about a topic or you have a question or a comment,
8 you could address that particular issue to the
9 Dockets Management address that appears in that
10 Federal Register notice.

11 At the registration table you should have
12 picked up an agenda also, and you will see on the
13 agenda that after the introductions we will have
14 some discussion of the draft guide, and throughout
15 the day there will be plenty of opportunity for
16 questions and answers. Toward the end of the
17 afternoon there will be an opportunity also for
18 statements from the public. So there will be
19 plenty of time for exchange of ideas.

20 Now let me give you a little bit of background
21 on the Food Safety Initiative and about this
22 particular meeting that we are conducting here
23 today. On October 2, 1997 President Clinton
24 announced the initiative to ensure the safety of
25 imported and domestic fruits and vegetables. As

1 part of this initiative the President directed the
2 Secretary of Health and Human Services in
3 partnership with the Secretary of Agriculture and
4 in close cooperation with the agricultural
5 community to issue guidance on good agricultural
6 practices or what we have come to call G-A-Ps or
7 GAPs and on good manufacturing practices,
8 traditionally called GMPs, but this time for fruits
9 and vegetables.

10 The Food and Drug Administration and the U.S.
11 Department of Agriculture have developed a proposed
12 guide that addresses microbial food safety hazards
13 and good management practices associated with
14 several things such as water quality, sanitation,
15 hygiene, transportation, manure, and municipal
16 biosolids common to the growing and harvesting of
17 most fruits and vegetables that are sold to
18 consumers in unprocessed and minimally processed
19 forms.

20 The draft guidance is intended to assist
21 growers and handlers in examining their operation
22 for potential microbial hazards, and it will also
23 assist in identifying management practice options
24 that may be adopted to minimize the risk of
25 microbial contamination from fresh produce.

1 Last December we sponsored a series of
2 grassroot meetings around the country to introduce
3 a working draft of the guide. In fact, one of
4 these meetings was held here in Florida in Palm
5 Beach County. We will review today, later on in
6 the program, comments received from at these
7 meetings. And the intention or the purpose of
8 today's meeting is to continue that process of
9 actively seeking input on the draft guide.

10 Saying that I would like to also explain that
11 three meetings such as this one are being
12 conducted, one of them already was held the day
13 before yesterday in Washington D.C. This one here
14 in Homestead, Florida is the second meeting, and
15 next week on May 27th there will be a third meeting
16 to be conducted in San Diego, California.

17 The draft guide, if you look on the
18 registration table, you will see that it has been
19 translated into Spanish, so it is available in
20 Spanish and English at this time and we expect to
21 have a French version available by the end of May.
22 Both translations as well as the English version
23 will be posted on the FDA web site in the
24 internet. For those of you who still are not very
25 familiar with the FDA home page, the address is

1 WWW.FDA.GOV. For this meeting here we have also
2 prepared slides for some part of the presentation
3 in Spanish, so there will be a part of the agenda
4 in which you will see simultaneous slides in
5 English and Spanish.

6 Today's meeting has been structured to
7 maximize your participation. There will be, as I
8 said before, plenty of opportunity to give your
9 comments and ask questions after each presentation.
10 We are most interested in your comments and
11 reactions to the draft guide. And like I said
12 before, if you get home and think of something in
13 addition to what you said here, you can submit your
14 written comment to the FDA following the
15 information on the Federal Register announcement,
16 just make sure that you include the docket number
17 on your comment.

18 If you look to this side of the room you will
19 see that the meeting is being transcribed so that
20 our development team can review all your comments
21 and make revisions to the draft guide as
22 appropriate. Also for the benefit of the person
23 transcribing I'm going to ask that when you have a
24 question or comment, and I would like to point out
25 that there is a floor microphone in the center

1 aisle, please come to the center to the floor
2 microphone and identify yourself and, if possible,
3 our transcriber would appreciate it if spell your
4 name.

5 For question and answer purposes we also have
6 some forms that Frank, one of your FDA public
7 affairs specialist, who is standing in back of the
8 room, Frank has some forms for questions. If you
9 think of a question while a presentation is going
10 on, please obtain a form from Frank so you can
11 write your question so you don't forget it and that
12 will be addressed in the question and answer
13 period.

14 Let's see. That's about all I have to say in
15 this brief introduction, which is not that brief
16 anymore. Again, the atmosphere, we want it to be
17 informal. Feel at home, feel free to make any
18 comments during the comment period. And now I'm
19 going to introduce the speakers at the table
20 currently.

21 The first person on my left is Dr. Lou Carson
22 from the Food and Drug Administration. He's a
23 Deputy Director of the Food Safety Initiative.

24 Next to Lou Carson is my "Jefe", Doug Tolen.
25 He's the District Director for the Florida District

1 of the Food and Drug Administration. His office is
2 in Orlando.

3 Next we have Dr. Martha Roberts. Dr. Roberts
4 is the Florida State Department of Agriculture and
5 Consumer Services, Deputy Commissioner for Food
6 Safety. And I think she does not really need an
7 introduction because I saw everybody greeting her
8 when she came in.

9 And next to Dr. Roberts we have Donald Pybas.
10 Don is the Director of the Miami-Dade County
11 Cooperative Extension Service, and he's been
12 working with us for several years now. And we'd
13 really like to appreciate at this time the
14 Extension hosting the meeting here at the
15 Agriculture Service. So now I would ask Lou to
16 please come to the podium.

17 MR. CARSON: Thank you very much, Estela.
18 Good morning. My name is Lou Carson. I'm Deputy
19 Director of the Food and Drug Administration, Food
20 Safety Initiative Staff, and I want to thank
21 Estela, State of Florida and Mr. Pybas for holding
22 this meeting here.

23 As Estela mentioned, the Food Safety
24 Initiative announced by the President last year is
25 a inner agency and State and local food safety

1 system program. We in the Food and Drug
2 Administration, our colleagues at USDA, both the
3 Extension Service, foreign ag service, food safety
4 and inspection service and the State and local
5 levels, are working together to achieve the goal
6 that the President set forth, and that goal was to
7 reduce to the greatest extent possible microbial
8 contamination of foods. And in particular today we
9 are talking about fresh and fresh cut produce that
10 may cause foodborne illness.

11 There have been a number of reported and an
12 increasing number of reports of foodborne illnesses
13 associated with fresh produce, and so over and
14 above the Food Safety Initiative the President
15 announced last year, in October he announced a
16 directive to the Food and Drug Administration and
17 the Department of Agriculture to work together in
18 promoting and developing good agricultural
19 practices.

20 The meeting today is another of a series of
21 meetings that we've held around the country where
22 we want to get grower, producer, consumer input
23 into how best to develop and how best to deliver
24 these good agricultural practices, so that we can
25 make an improvement in the food safety network and

1 consumers can feel assured that the food that they
2 receive is both nutritious, healthy and safe.

3 We at the Food and Drug Administration have
4 developed, again with our colleagues at the State
5 and local level, at the other Federal levels, the
6 document that we have before us today to discuss.
7 I think as Estela mentioned, we want to make this
8 as informal and as interactive a process as
9 possible. This meeting is important to us, to add
10 to the record, to understand from the grower and
11 consumer perspective how these agricultural
12 practices may be applied, what they should say and
13 to give us as good a feel for agricultural
14 practices that are currently being used today.

15 In association with these meetings we and our
16 colleagues are also going on a number of site
17 visits to farms around the country, and we are
18 pleased to be doing that tomorrow. Again, that
19 will help us better understand the agricultural
20 practice and better translate that into words
21 within the document.

22 I want to encourage you to speak today,
23 because as Estela mentioned, this session is being
24 transcribed. We need your input so that this
25 document can be as good as possible. Our process

1 is that we are seeking comments through June 29th,
2 both in these public meetings and as comments to
3 the dockets as Estela mentioned. Following that we
4 will be working with our development team to come
5 up with the final guide, which we hope to publish
6 in October.

7 That final guide is simply a guide -- these
8 are voluntary guidelines, and that final guide is a
9 starting point. It is not the last guide you will
10 see. As a voluntary guidance it must updated as we
11 learn more about the science, both from the risk
12 assessment and from the science based information
13 on the microorganisms that may or may not be on
14 that fresh produce. So we fully expect that this
15 guide will be a living document that will have many
16 iterations and updates as we learn more about the
17 microecology of these microorganisms and that fresh
18 produce.

19 We also want to learn from industry as these
20 practices were applied and where things work and
21 where thing did not work, and we need to get that
22 input so that we can make this document as good as
23 it can be. So again, I encourage you to be
24 forthcoming today, to provide your comments,
25 questions. To the extent we can answer those

1 questions, we will. And we really do want to hear
2 all that you have to say and that's why we are here
3 today, so I encourage you to do that. Thank you.

4 MR. TOLEN: Good morning and welcome. We have
5 done a number of these programs in South Florida
6 over a number of years, and this is one of many
7 that we've done here since I came down as Florida's
8 director in 1986. Some of you have probably
9 participated in a variety of programs we've done in
10 the past, and I welcome you. We'll make this as
11 informal as we can. I've taken my coat off, I'm
12 not wearing short sleeves. I invite you to do the
13 same, including our speakers.

14 We have a relatively smaller audience than we
15 anticipated, although we may have some folks
16 arriving late, so I invite you to move forward if
17 you'd like and make this as intimate a workshop
18 process as we possibly can. So if you are having
19 trouble hearing and would like to be -- come get
20 closer to hear the answers to questions that would
21 be asked and answered, feel free to do so.

22 I'd like to mention just a minute or two
23 telling you about FDA and FDA Florida. I'm not
24 sure all of you know of the role of our agency as a
25 whole. We were created in 1906. We regulate the

1 U.S. food supply, both domestic, and I'm not going
2 to emphasize import because that's a big part of
3 what we do in the produce industry. Also all
4 prescription and nonprescription drugs, medical
5 devices and radiation emitting devices such as
6 X-ray ovens and X-ray equipment, so we have a wide
7 range of responsibilities.

8 The value of the goods that FDA regulates is
9 some 570 billion dollars every year. Now, I just
10 read an article the other day that said we import
11 in the United States 30 billion tons of food per
12 year. That's a lot of watermelons, a lot grapes,
13 if you will, and a lot of that comes through our
14 ports here in Florida. And we have import staff
15 both here in Miami, in Tampa and in Jacksonville
16 who are looking at this merchandize, as well as
17 domestic investigational staff who inspects some
18 6,000 domestic processors, manufacturers and
19 warehouses here in this state, and that's in
20 addition to what the State and local health
21 components do as well.

22 And how do we do that? On the domestic side
23 of the house my investigators, some 90 of them here
24 in Florida, go out and actually do physical
25 inspections at these manufacturing sites. On the

1 import side of the house we physically collect
2 samples as this merchandize comes in and it's sent
3 to a laboratory in Atlanta where they run that for
4 pesticides, multibiologic analyses, heavy metals,
5 labelling, what have you. So we are an important
6 process, important presence in the lives of
7 American consumers through the volume and value of
8 the products that we regulate.

9 Part of this process is getting involved in
10 the development of new guidance and regulations,
11 and as you've already heard, that's why you are
12 here today. We have a new guidance coming out, and
13 I want to emphasize as Lou already stated, because
14 this was a big concern in the past, this guidance
15 is not required, it's not compulsory, it is
16 voluntary on the part of both domestic and foreign
17 producers. So this guidance requires your input
18 and we value that.

19 This is one of three opportunities between now
20 and June 29th to have public comment, public input
21 to this document before it is finalized. So if
22 there's some part of these new guidelines that
23 bother you, as either a domestic farm or as a
24 foreign processor, industry association, here's the
25 opportunity to have your comments heard in a public

1 forum, an opportunity for our regulation writers to
2 look at those comments as they come in from these
3 various sites and make a determination as to
4 whether or not these guidelines should be modified
5 so that they are doable and usable by the industry
6 to which they are intended.

7 None of us are farmers, none of us are
8 growers, none of us are importers, we like you are
9 consumers of goods. We want to make sure they are
10 as safe as possible. My children eat produce just
11 like you and your children do, so we have equal
12 concerns. But here's an opportunity to come up
13 with some guidelines we can all live with, so
14 again, let me emphasize we solicit your input, we
15 invite your input and we appreciate your input.
16 Thank you.

17 MS. ROBERTS: Good morning. I'm Martha
18 Roberts. I'm one of the Deputy Commissioners of
19 the Florida Department of Agriculture and Consumer
20 Services and I'm very pleased to be here to welcome
21 you today, because safety of our food supply should
22 be the utmost concern to us, not only as
23 individuals, but to us as a nation.

24 We live with a global trading world today. We
25 have a global food supply. We must be concerned

1 about every source of food that we are consuming,
2 and again try to apply consistency in the way that
3 we deal with that. But we vary, definitely, and we
4 are proud here in the State of Florida of our
5 strong proactive food safety program and we are
6 proud of the multi billion dollar agriculture as of
7 what they produce of the food supply of this
8 country.

9 It's of critical importance, as we go through
10 the review of this document and as we consider this
11 subject, that we apply realistic common sense
12 guidance, not only to our domestic industry but to
13 those foods that we are importing from abroad. But
14 it is also critical that we have appropriate, not
15 only guidance to the producer, but that we have
16 appropriate guidance and education, not only to the
17 producing industry but to the general public. And
18 it's critical that we also require adherence of all
19 to the practices that we are outlining.

20 So this is the second of the three public
21 meetings, as you have had described to you, and
22 it's indeed an opportunity for you to raise your
23 voice and support the document, as a voice of
24 concern about some specific aspect of the
25 document. I know a good many of you in the room.

1 I know that many of you are not shy. This is your
2 chance to have a public statement, either in
3 support or of your concerns and it's a rare
4 opportunity.

5 And I do commend the Food and Drug
6 Administration for having this public meeting here
7 in Homestead, because it is most appropriate that
8 this public meeting be held here, in a community
9 where the very basis and the life blood of this
10 community is agriculture. It is very appropriate
11 that one of these public meeting be held here
12 because this is an area of the United States in the
13 winter months that produces 95 to 98 percent of
14 some of the specific fruit and vegetable
15 commodities that we are talking about that are
16 grown domestically. This rest of that supply of
17 those fruits and vegetables come from other
18 countries during the winter months.

19 My father was a local newspaper editor back
20 here in Homestead in 1939, 1940. He wrote a small
21 town article about the comings and goings in the
22 community. It was an ag community then. The life
23 blood of this community is still agriculture, still
24 the very fruits and vegetables that this document
25 speaks about. So it's the very area where the

1 farmers are producing the health giving, the cancer
2 and disease fighting fruits and vegetables that we
3 need to consume more of, but yet that we must
4 produce in a safe manner.

5 So again, we are delighted that it's here in
6 Homestead, but I want to commend FDA also for not
7 only the willingness to have it here in Homestead,
8 but for the willingness to involve others. This is
9 a Federal document. The Food and Drug
10 Administration did not have to involve us in State
11 government, they did not have to involve us, some
12 of you out there in Florida industry, but they did.

13 They came to us and asked us for input early
14 on with some early drafts, and we were able to
15 provide some input and some comments and to maybe
16 have a little redirection and thought or
17 often-times mention things that maybe were not
18 common sense if you are actually out in a farming
19 situation and they very willingly took some of that
20 input, and I want to publicly tell them that we
21 appreciate that. And we also appreciate their
22 willingness to go out in a real life farming
23 situation with some of the scientists and some of
24 the committees dealing with this, to see what is
25 required in producing and harvesting and packing a

1 product on a real farm.

2 So we are delighted that they've allowed the
3 participation not only of our State of Florida, but
4 of California. And we ask them, as has been
5 permitted to you, for their continued willingness
6 to listen to those involved in food safety as it is
7 implemented in the marketplace and in State
8 government and food safety practices as they are
9 implemented on the farm.

10 And I'd be real negligent if I didn't commend
11 the farming industry, certainly from personal
12 experience in the State of Florida, because I know
13 that there have been a tremendous number of
14 practices that are in this document that have
15 already been common sense practices, industry has
16 done this for years. There are other new
17 suggestions that the industry has on the initiative
18 implemented, and I know of these growers right now
19 that can even trace back their product to the
20 individual picker on a farm. And so I commend the
21 industry for their willingness to work in
22 partnership with State and Federal regulatory
23 agencies to achieve the safety of the foods we eat.

24 So on behalf of Commissioner Bob Crawford,
25 Commissioner of Agriculture of the State of

1 Florida, on behalf of the six billion dollar
2 agricultural industry, to the 54 billion dollar
3 economic impact of this state and on behalf of the
4 very proactive and excellent food safety
5 professionals we have at the Department of
6 Agriculture and Consumer Services and Inspection
7 and Testing Program, I welcome you to the State of
8 Florida and to the second of three public meetings
9 and I urge you to not be reticent in your comments
10 either verbally today or in writing to the Food and
11 Drug Administration and what you feel needs to be a
12 part of this document, thank you.

13 MR. PYBAS: My name is Don Pybas, I'm the
14 County Extension Director. I direct this facility
15 that we are meeting in today. We are very
16 privileged to have the opportunity to host this
17 meeting. As Dr. Roberts indicated it's very
18 significant that we are having this meeting here in
19 Homestead, center of a very large agricultural
20 industry down here.

21 We in 1995, 1996, Dade County, Miami-Dade
22 County as it's now called, had about an 860 million
23 dollar economic impact from agriculture. This was
24 a very significant sector of the economy and in
25 particular in the south end of the county, a very

1 big employer, so we are very fortunate to have this
2 meeting here. I think it's very apropos for this
3 industry.

4 As far as the Extension Service, we enrolled
5 in this program today and also any subsequent
6 activity of -- the Extension Service has been
7 around a long time and it's very appropriate to say
8 that, you know, we were first created by Congress
9 and USDA in 1914, by an act of Congress, and the
10 first extension agent down here was a home canning
11 agent, it was not an agricultural agent. And food
12 preservation was a key thing in the
13 prerefrigeration days, the early teens or early
14 part of the century, so it's kind of interesting to
15 see that we had people here as educators helping
16 people preserve the foods as they grew it on farms
17 here in South Florida as well as small types of
18 commodities.

19 So today the Extension in this county has 16
20 professional agents, several of which are in the
21 audience today. We have a couple of our Food
22 Science and Human Nutrition Agents, if you can
23 stand. It's Jan Gibson and Monica Dawkins, they
24 both work in the area of food and nutrition and
25 also food handler and food safety training.

1 In another part of the room are a couple of my
2 ag agents here. Dr. Carlos Balerdi is a Tropical
3 foods agent, and Teresa Olczyk is one of our
4 vegetable agents that works with a lot of post
5 production as well as trials on varieties and other
6 types of programs. We have other commercial
7 commodity agents here in this office as well as the
8 other offices we have here in Dade County. We have
9 four offices here. We are one of the largest
10 staffs in the Extension.

11 Our role, as I indicated a little bit earlier
12 is a little different than the rest of the
13 agencies, FDA, USDA and the State Department of the
14 Agriculture and Consumer Services. We are one
15 that-- we are education and information
16 dissemination, that's our job. We are affiliated
17 with the University of Florida in part of the
18 land-grant system, and we do an extensive amount of
19 training and education opportunities through this
20 facility right here, as well as on field, out in
21 the field demonstrations, those kinds of things.

22 We are not a regulatory type of an agency. We
23 do not enforce or regulate growers or any of our
24 clientele. We are here to assist them in
25 disseminating information such as the draft

1 guidance documents and other types of training
2 programs. We do the pesticide training program for
3 the State of Florida here in this county, in this
4 facility for all of the pesticide users that are
5 used in the district of pesticide.

6 So we feel like we have a role here to educate
7 and disseminate information and we will continue to
8 work with the agency to do that. There's a little
9 bit -- it's going back to the agricultural aspect
10 of this community. We do have a centennial of
11 agriculture that's going on here in the Red Lands,
12 which is this general area that we are in, South
13 Dade. We do have information on a lot of the
14 activities here out at the counter, in the
15 registration counter out there. We hand out
16 material on that. We are very proud of this
17 industry and participating in the centennial
18 activities as a board member of that group.

19 Also for your information, if you are not
20 familiar with the Extension Service there is a
21 brochure on what we do and how we are affiliated
22 with the University of Florida as well as Dade
23 County or Miami-Dade County and USDA. So if you'd
24 like either of these, they are out on the counter
25 there, thank you. And if you there's anything else

1 that we can do as far as providing some
2 accommodations or whatever, we do have information
3 on the restaurants. If you are interested and you
4 are not familiar with the area, there is a map with
5 a list of restaurants in back of the rooms. Also,
6 the restrooms are in the lobby area. If those
7 become too busy, we do have additional restrooms in
8 back of the facility. If you go down the hallway
9 through the lobby they are all the way in the back.
10 The pay phone is out in the lobby by the soda
11 machines. Anything we can do to assist you, please
12 feel free to ask, thank you.

13 MS. NIELLA-BROWN: After the introductions now
14 on the agenda we have an update on the development
15 of the draft guide, and Lou Carson from FDA will be
16 covering that topic.

17 MR. CARSON: Thank you again, Estela. Much
18 has already been said about how we got here today,
19 but let me review the process. We started back in
20 November, November 17th, and had a public meeting
21 in Virginia to talk to the committee about the
22 overall concepts of the good agricultural practice
23 document that we have here today.

24 Following that meeting and getting the input
25 from industry consumer groups, we also met with the

1 National Advisory Committee for Microcriterion
2 Foods, which is an inner agency, Federal scientific
3 body, that advises different agencies on scientific
4 issues, so we wanted to also apprise them of what
5 we were doing and to get some input into our draft
6 guide. On November 25th we published that working
7 draft guide for comment and we received
8 approximately 55 written comments to the docket.

9 In the six or seven public meetings that we
10 held over 400 individuals attended those meetings
11 and those transcripts were also gotten, so that we
12 can review the comments that were made at that
13 time. We convened a Federal and State development
14 work group. We had individuals from Departments of
15 Agriculture and Health, from the states of
16 California, Michigan and Florida, along with OSHA,
17 Department of Agriculture, EPA and the Food and
18 Drug Administration to review all of those comments
19 and to assess what it is we had in the guide and
20 how we can best refine it to more appropriately
21 describe what we were trying to get across.

22 That input from our colleagues was invaluable,
23 and later on I believe Dr. Smith will also talk
24 about how we were able to, I think, refine this
25 document appropriately, based on that substantive

1 input. We then tried to put together the guide
2 based on all of that input, and then there were
3 several affidavits that were circulated into that
4 development team and a broader array of Federal and
5 State scientists so we could have good input into
6 the document. April 13th we published the draft
7 guide that you have in your package today.

8 I think the panel that's here at the table
9 truly represents a broad array of people that we
10 are trying to reach and tried to work with. During
11 this period of time we've also worked with trade
12 associations, Western Growers, United Fresh Fruits
13 and Vegetables and the Foreign Trade Fresh Fruit
14 and Vegetables of America, in trying to best
15 understand from their perspective how best this
16 guide can be applied. So we have strived to do a
17 number of outreach activities so that we would
18 engage industry and make sure that the industry
19 understood that we really did want them to work
20 with us as partners on this guide.

21 This meeting today, again, is an effort to
22 engage industry and consumers in being a partner on
23 this guide. We recognize the guide must be as
24 practicable and common sense as Marty Roberts said,
25 so that it will be utilized. If it is impractical,

1 we recognize that it will never be adopted or
2 applied. So our purpose here is to get the most
3 practical and have a guide possible and have an
4 output that really does improve the overall safety
5 of fresh fruits and vegetables.

6 As we are developing this guide we need to
7 come up with a mechanism so that we could determine
8 what is -- what are the agricultural practices, not
9 only in this country but around the world, and to
10 see what impact the guide will have. We are
11 currently working with the National Agricultural
12 Statistic Services and the Department of
13 Agriculture to put together a survey, and this
14 survey is like the ones they do currently for
15 pesticides and other commodity issues to get a
16 sense of what the agricultural practices are, so
17 that we can better understand those practices.

18 We are pursuing this effort in the next fiscal
19 year with the National Agriculture Statistic
20 Service, and again, it will be a survey through
21 NASDA, National Association of State Department of
22 Agriculture, as they do other surveys, and it will
23 simply be to get a catalog of the agricultural
24 practices and then in several years later to see if
25 the guide, in whatever form it is then, has had a

1 material impact.

2 We are not here to assess what a good practice
3 is and what a bad practice is, we are here to
4 assess whether the guide has made a material
5 difference, whether the guide, which we are putting
6 forward today, first sets awareness. If producers
7 become better aware that the commodities, the food
8 that they produce must be produced in a certain
9 manner so that they are as safe, nutritious and
10 healthy as possible.

11 So the survey that we are trying to put
12 forward with the Department of Agriculture's
13 assistance is simply to give us a measurement on
14 these voluntary guides. We recognize they are
15 voluntary, not everyone will apply them, but we
16 want to see if there is some measurable impact.

17 We are also working with our colleagues in the
18 foreign ag service, State Department and elsewhere
19 to see how best we can approach the foreign
20 producers with the same survey instrument and to,
21 again, get a sense of the foreign agricultural
22 practices. This is somewhat of a daunting task.
23 It's a big world out there, but we do need to get
24 some sense of what the ag practices are so that we
25 can see that this document does have validity. We

1 need to make sure that the document is making a
2 difference. And if it's not, then we need to be
3 able to change it so it will make a difference.

4 So our whole purpose in using the guide and in
5 doing the survey is to try and make all producers
6 and consumers aware that there are some
7 possibilities, some potentials with fresh produce
8 to cause foodborne illness, but by and large food
9 is produced in a safe and healthy manner, and
10 especially if these particular steps are taken, we
11 can ensure that to a greater extent.

12 The program that we have set up for you today
13 has this first panel and then our next panel will
14 be our different colleagues talking about the means
15 and mechanisms that we are looking at to further
16 promote and distribute good agricultural
17 practices. And then this afternoon we will be
18 going over the guide in section by section detail,
19 and we really encourage you to stay this afternoon
20 to discuss the guide in detail so that we can get
21 that valuable input there. Thank you.

22 MS. NIELLA-BROWN: At this time we have an
23 opportunity for questions and answers on the
24 development update. Is there any question at this
25 point?

1 MS. GILLEN: Hi, there. My name is Michelle
2 Gillen and I represent WFOR, the CBS station here
3 the Miami, I have a few specifics about the
4 program. I know we'll be going through it, but let
5 me just for starters begin, Mr. Carson, I know you
6 just mentioned that by and large most produce is
7 produced in a safe manner. I'd like get your
8 reaction to the results of the recent GAO report
9 that spoke to the fact that at least in the
10 report's opinions that foreign produce, the Federal
11 government cannot guarantee the safety of foreign
12 produce today, and vis-a-vis the point that only
13 two percent of it is being inspected by authorities
14 here in the United States. I'd like to know your
15 reaction to that, if there's any concern regarding
16 that by panel members.

17 MR. CARSON: I believe the Food and Drug
18 Administration made a formal statement and public
19 statement concerning the GAO report. By and large
20 what we have said is much of what the GAO report
21 has recognized within the food safety system is
22 that the level of resources, which the Food and
23 Drug Administration and other Federal and State
24 agencies have to devote to imports, is
25 diminishing. And that because we have such small

1 resources, the level of affirmative steps to ensure
2 that the produce is safe is lacking.

3 But let me take a further step and say that by
4 and large the Food and Drug Administration
5 recognizes that the industry has the major
6 responsibility in producing safe, wholesome and
7 nutritious food. We as a government agency are
8 here to ensure that those practices are being
9 upheld. With foreign firms, obviously, we do not
10 have inspectors abroad, but all we are trying to
11 say is, what the GAO is trying to say is, we need
12 to have more information as to how produce is being
13 produced, but we do not have any information that
14 foreign produce is produced in any less quality
15 manner than it is here in the United States.

16 MS. GILLEN: But the result of the report
17 though contradicts that, sir, and says that under
18 the current system the Federal government cannot
19 guarantee the safety of them and I quote directly
20 from the report, so I least --

21 MR. CARSON: I don't know that we can
22 guarantee the safety, we only analyze a very small
23 portion of any food product. And again, as I said,
24 I believe that it is industry's responsibility to
25 guarantee its product.

1 MS. GILLEN: My questions, again, is just is
2 it acceptable to you that our government, at this
3 time inspects only two percent of foreign produce?
4 Is that acceptable? Should it be acceptable?

5 MR. CARSON: We believe we can do better. We
6 believe we should do more. We are doing as good a
7 job as we can with the resources we have
8 available. If we are looking at the issues today
9 we are here to discuss, the only way we can make an
10 impact on improving food safety is not by testing
11 end product, but through prevention. We believe
12 our approach is through preventive systems, such as
13 good agricultural practices. We have come out with
14 a number of regulations on juice and eggs so that
15 food can be produced and through that production we
16 can assure that food is safe.

17 There is no amount of resources that would
18 allow the Food and Drug Administration or any
19 government agency to test each and every food
20 product. If you are asking --

21 MS. GILLEN: It's just I think the American
22 public is expecting more than two percent. I know
23 you want to deal with specific comments, so let
24 me-- as you were saying deals with of course we
25 can't have inspectors in every country, I just want

1 to follow up and then I certainly would relinquish
2 the microphone.

3 A good portion of the guideline that deals
4 with the importance of sanitation, and what I got
5 from it through reading was a lot of emphasis seems
6 to be on workers, the emphasis on the report, the
7 guidelines, seems to be on workers washing their
8 hands after using the bathroom, and I just wonder
9 if that side step is a reality issue in some
10 country such as Mexico, where we spent a good deal
11 of time, where there are no handwashing facilities
12 or often there are no toilets. So if their
13 recommendation is just for workers having to wash
14 their hands, the workers in the field will tell you
15 very freely, there's nowhere to wash their hands,
16 there's often nowhere to go to the bathroom other
17 than the field. Why does this guideline not
18 address that and should it?

19 MR. CARSON: Well, I beg to differ, because I
20 believe the guideline specifically does have worker
21 health and hygiene, and we do talk about toilet
22 facilities.

23 MS. GILLEN: But it only makes reference to
24 U.S. law and countries like Mexico are not
25 regulated by U.S. law.

1 MR. CARSON: As we are doing in this guide, we
2 are recommending good agricultural practice, not
3 only for the domestic industry but for the foreign
4 industry. These good agricultural practice
5 guidelines, which are voluntary, will apply
6 domestically and internationally. And as I said,
7 our next panel will discuss means and mechanisms
8 that we are trying to use to promote these
9 internationally. I would not agree with your
10 summary of the facilities abroad as you have
11 described them, because we do receive quite a large
12 amount of foreign produce during the winter months,
13 which Southern Florida here also contributes to.
14 And if you look at the data, the amount of
15 foodborne illness is not as high as you would
16 expect, if the conditions are as you've described
17 them.

18 We do recognize that food handling is a
19 significant contributor to foodborne illness, and
20 we are addressing that within this guide. It is
21 well known, whether it's in a hospital setting or
22 in a field setting, if people do not wash their
23 hands infections increase.

24 MS. GILLEN: Are you aware of the fact that
25 FDA inspectors have gone to Mexico and confirmed

1 that in some fields are no handwashing facilities?
2 Are you aware there have been inspectors in the
3 past year and-a-half that went there and formally
4 voiced concerns over that?

5 MR. CARSON: I'm not sure exactly which
6 incident. We have visited abroad, but our only
7 purpose when visiting abroad is tracing back if
8 there is a problem with a particular food product.
9 We by and large do not inspect foreign farms unless
10 they are specifically under --

11 MS. GILLEN: I'm not saying you do, I'm just
12 saying that --

13 MR. CARSON: I'm not an FDA inspector, I'm not
14 aware of FDA inspectors, per se, going to foreign
15 farms and looking at that. I do know the State of
16 California and others based on the strawberry
17 incident, have gone to Mexican farms and
18 investigated certain Mexican farms, based on the
19 incident with Hepatitis A and frozen strawberries.

20 MS. GILLEN: Are you aware of any reports that
21 came back over regarding the concern over the lack
22 of handwashing facilities and sanitation
23 conditions?

24 MR. CARSON: I am certainly aware of all of
25 the reports. I am certainly aware of what

1 California is doing in that industry. I'm
2 certainly aware of what we are doing with the
3 Mexican officials to ensure that their practices
4 and what they are doing through their government
5 and through their trade associations are consistent
6 with what we expect for good, safe food to come
7 into this country, but I'm not sure if you have a
8 specific instance in mind.

9 MS. GILLEN: Yeah. Actually I've been trying
10 to get some of that information back for six
11 months. In the congressional hearing after the
12 strawberry incident, it was Doctor -- I think it
13 was Frank Shantz (phonetic) from the FDA or you are
14 familiar with his name, I'm sure. Dr. Roberts, she
15 must know who I'm talking about.

16 MS. ROBERTS: Dr. Fred Shantz?

17 MS. GILLEN: Dr. Fred Shantz, yes. He was
18 before the congressional hearing and answered the
19 question and specifically spoke of the fact that
20 some of his investigators had gone to Mexico and
21 indeed expressed concerns over the lack of
22 sanitation and handwashing conditions. I've been
23 trying to follow up on that investigation all these
24 months and have been told they have free
25 inspections, and I just wondered, given your

1 prestigious position on this panel, given the part
2 of the FDA, if anyone has ever filled you in on
3 those findings he spoke of?

4 MR. CARSON: Dr. Shantz was responding to a
5 specific instance where we followed up on foodborne
6 illness and which we did investigate in a
7 particular farm and those findings were based on
8 that investigation.

9 MS. GILLEN: And those findings are, sir?

10 MR. CARSON: I don't have them in front of me.
11 I can't quote for them.

12 MS. GILLEN: In general is it what I've been
13 saying, that they did in those cases find concern
14 over the lack of handwashing?

15 MR. CARSON: I can't without the record in
16 front of me. What I wanted to say is, to this date
17 with the Hepatitis A and strawberries neither the
18 Food and Drug Administration nor the Center for
19 Disease Control nor anyone has pinpointed the
20 source of that contamination. We still do not know
21 if that source was in Mexico or in California or
22 elsewhere.

23 MS. GILLEN: But it's still --

24 MR. CARSON: That source has never been
25 determined, that's my point. I do not have the

1 specifics in front of me as to know if he cited
2 handwashing facilities or whatever. Certainly
3 Hepatitis A can be conveyed through poor worker
4 hygiene and practices. There have been other
5 Hepatitis A outbreaks that are associated with U.S.
6 produce.

7 MS. GILLEN: I'm in no way saying that U.S.
8 produce because it's domestic is safe, and I'll sit
9 down, but my point is just on the various specific
10 incidents, should part of the guidelines deal with
11 sanitation. Those words that were set before the
12 congressional panel I thought were rather important
13 and I just was curious --

14 MR. CARSON: Well, we certainly think they are
15 important and that's why we have the Food Safety
16 Initiative and that's why we have the produce
17 initiative. We believe that particular steps must
18 be taken, both domestically and internationally, to
19 ensure that that does not occur. But I do not have
20 the specifics in front of me to respond to that
21 specific instance that you are talking about.

22 MS. PEAL: Good morning, everybody. I'm Vicky
23 Peal. I paid my admission dearly to be here today,
24 I took my Dad out for dinner and killed him and I
25 just don't want it to happen to any other members

1 of my family. I usually speak in Washington and
2 it's the greatest honor to be here in the State of
3 Florida, the state of conscience and culpability
4 for so many wonderful practices we put ahead and I
5 am proud to be a member of this state. I just wish
6 the other 49 states would follow through in many
7 instances.

8 There are a couple of things that have already
9 been stated that have alarmed me this morning, one
10 of those statements were that industry is charged
11 to help make sure we have safe food, and the other
12 one that FDA didn't have to invite us here today.
13 You're paid by the people in this country to keep
14 us safe, not industry, and to do anything but that,
15 to let any other agenda get in your way implies
16 that your priorities lie elsewhere. We have over
17 9,000 deaths annually, and those are the ones that
18 are reported and we know we are under reporting.
19 They shouldn't be happening and until you
20 demonstrate that you have a clear focus to all the
21 dangerous situations at hand, we are going to be
22 very, very concerned.

23 The only other thing I want to say, and I hope
24 to be speaking later and I want us to focus upon
25 this, is that your main goal is to have this guide

1 produce measures that will have an impact on my
2 safety, my family's safety and the safety of
3 everyone in this room. You are going to study and
4 study and study, what are you going to do until a
5 guide comes out with definitive statements? Are
6 you just going to take a body count? We need to
7 have measures happening right now, today. Please,
8 as we go toward today we need answers, not more
9 studying. Thank you.

10 MS. NIELLA-BROWN: While the next person comes
11 in, I just want to say, at this point let's try to
12 keep the questions limited to whatever has been
13 discussed now and later on during the afternoon
14 there will be an opportunity for other statements,
15 but at this point let's try to keep the questions
16 limited to the draft guide and comments from the
17 draft guide.

18 Also, again, let me mention that there are
19 forms to write the questions, Camille has them now
20 and I believe Frank has them also. If you would
21 please write the question, that will make it
22 easier. We are going to have one more question
23 right now and then we are going to have to move on
24 in order to keep the agenda moving. Go ahead.

25 MR. VUCETICH: My name is Ian Vucetich, I-a-n

1 V-u-c-e-t-i-c-h, from SGS Control Services
2 worldwide inspection and standard company. We've
3 been following the Food Safety Initiative from the
4 start very closely and we have basically a foreign
5 produce concern and is basically three concerns
6 which is voluntary compliance, voluntary compliance
7 and voluntary compliance. And my questions are
8 basically -- my suggestion would be, what if the
9 Food Safety Initiative if more collaboration with
10 private enterprises for more controlled inspections
11 of foreign countries could be done? I know
12 resources of FDA are limited in this regard.

13 MS. NIELLA-BROWN: You had a question, right?

14 MR. CARSON: Is there a question?

15 MR. VUCETICH: It's a comment on whether the
16 FDA should collaborate more closely with
17 independent companies and help on inspections and
18 control, because, for example, the Food Safety
19 Initiative fell short of recommending Haccap for
20 foods and vegetables, I know it's recommended for
21 meat and poultry, and the question is why didn't
22 they go that extent to recommend it for foreign
23 produce?

24 MR. CARSON: Okay. Thank you for you
25 comments. Again, the Food and Drug Administration

1 applies standards to the best of its ability based
2 on the best science available. We have, through
3 the Food Safety Initiative, initiated seafood
4 Haccap this last December. We recently came out
5 with a proposed guide on juice Haccap and juice
6 labelling, and we have also recently come out with
7 eggs labelling and eventually will be an eggs
8 Haccap along with our colleagues at USDA.

9 In the arena of fresh fruits and vegetables
10 the research science makes for our understanding of
11 how microorganisms become pathogenic, when they
12 become pathogenic, is still very much unknown. We
13 have really a deficit of science to base definitive
14 steps which Haccap requires. Haccap is a
15 preventive system. We cannot just say don't do
16 this, Haccap has to require a statement of what
17 should the producer do. What are the vectors? What
18 are the microorganisms that they need to be aware
19 of and how should they treat their water, manure or
20 whatever in order that they minimize that
21 possibility?

22 We are undertaking a large inner agency
23 research program to try and answer those questions
24 as soon as possible. We recognize that we need to
25 deliver positive techniques, technologies to the

1 industry so that they can employ them.

2 We are, I think, working through the industry
3 in many ways. We convened an industry research
4 meeting last October. We asked industry what
5 research they are conducting, we asked them what
6 they felt the priorities were in resolving some of
7 the very difficult scientific issues confronting
8 us. We based our research program on priorities
9 that they identified, which they were not meeting,
10 they were not able to follow through on, as well as
11 the ones that the Federal government also feels is
12 very important, and we will be coming out with a
13 research program to show what it is we need to
14 follow through on.

15 The guide represents the best science we have
16 today through those vectors that we know from past
17 practices and science that may contribute
18 microorganisms to fresh produce, and the fact that
19 fresh produce is not further treated so that it
20 would reduce those microorganism. We need to make
21 people aware of those particular vectors; water,
22 worker sanitation, facilities sanitation,
23 transportation, manure and likewise. And that's
24 what the guide comprises. So I believe we are
25 trying to make those connections with public and

1 private industry and are working academia.

2 It's true, we at FDA do not have all the
3 answers. We are trying to have a collaborative
4 research effort with all the best scientists in the
5 world to come to grips with those products and to
6 resolve them.

7 MS. NIELLA-BROWN: At this time the agenda
8 calls for a break. We are running a little bit
9 late so instead of a 15 minute break let's just
10 take a ten minute break and be back here by 11:30.

11 (Thereupon a recess was taken in the
12 proceedings, after which the deposition
13 continued as follows:)

14 MR. TOLEN: We lost some time here so we want
15 to move forward as quickly as possible so we can
16 meet our time frame and complete our program and
17 provide you with the opportunity to have your input
18 as well.

19 The next set on the agenda is a panel
20 discussion about the public health significance of
21 good agricultural practice. We want to cover a
22 couple of things here. There are four areas we'd
23 like to concentrate on, and if we tend to run a
24 little long, what I'm going to suggest we do is
25 maybe take a lunch break before we complete this

1 activity and perhaps pick up the last speaker or
2 two after lunch. So Estela, kind of watch the time
3 and give me a signal when we get about when it's
4 time to break for lunch. The reason we'll do that
5 is we want to get you to lunch fairly quickly
6 before the crowds hit, so we get back in time to
7 complete the afternoon program and spend as much
8 time as possible for Q and A. So we may take a
9 lunch break at some midpoint in this next set of
10 presentations.

11 What we intend to cover on our next part of
12 the program is to examine the importance of good
13 agricultural practices, in meeting them, that the
14 broad public health goal of improving food safety
15 and reducing foodborne illnesses. We want to
16 explore some examples of how we might cooperate
17 internationally to make that happen, and we also
18 want to talk about some model which we might use to
19 disseminate information both from the domestic
20 front and on the international front to make sure
21 that the folks who need to have the information,
22 who need to have that technical assistance,
23 wherever they may be in the food chain and finally
24 the last item we are going to chat about a little
25 bit is not on the agenda, is traceback mechanics,

1 which is part of any investigation on foodborne
2 illness, and I'll speak to that lastly.

3 Our panel to do that, again, on the panel here
4 from my left Lou Carson will be with us again, and
5 you all know Lou well by now, but next to him is
6 Ricardo Gomez from the United State Department of
7 Agriculture. He's the Chief Holticulturalist with
8 the Cooperative State Research Education and
9 Extension Service.

10 To his left is Dr. Wayne Derstine. Dr.
11 Derstine is with the Florida State Department of
12 Agriculture and Consumer Services, and he's the
13 Environmental Administrator for the Food Inspection
14 Unit there.

15 And to his left is Lloyd Harbert, also from
16 the United States Department of Agriculture, and
17 Lloyd is the director of the Food Safety and
18 Technical Division, Foreign Agriculture Service.
19 He's one of those folks who represent us in foreign
20 lands, just happened to come back from a tour in
21 London. And then I'll be joining the panel in
22 traceback as well.

23 Let's start again with Lou to talk about the
24 food safety issue overall.

25 MR. CARSON: The purpose of my talk right now

1 is to put the produce initiative which the
2 President announced in October into context of the
3 overall Food Safety Initiative. Last year in
4 January the President announced the Food Safety
5 Initiative and he convened a group of consumers,
6 industry and Federal, State governments and
7 government professionals together to produce a
8 report to him in May which outlined the Food Safety
9 Initiative.

10 There are six areas that we hope to devote
11 more attention to, the first one is surveillance.
12 Surveillance is the system established by the
13 Center for Disease Control called the food net
14 sentinel sightings, and there are seven of those
15 around the country in which active surveillance,
16 surveys of hospitals, physicians and other health
17 care professionals are conducted so that we can
18 have an early warning system of foodborne illnesses
19 and that information would get back to the Food and
20 Drug Administration and the Department of
21 Agriculture for us to follow up on to see whether
22 our products were involved and to what extent those
23 products contributed to the illness.

24 I need to let you know that within food net,
25 as we improve that system, the number and the

1 frequency of foodborne illnesses reportings is
2 bound to increase, but that increase is not
3 necessarily that food is getting worse, it's simply
4 that the system is improving. Previous to the Food
5 Safety Initiative the system for surveillance of
6 foodborne illnesses was a passive system, a system
7 set up by the Center for Disease Control where
8 State and local health departments sent in a piece
9 of paper, which was then cumulated and then
10 assembled into a data base and then someone finally
11 evaluated it, a very slow deliberate process. As
12 with foodborne illnesses it's very hard to link a
13 foodborne illness of one individual here in
14 Homestead with one up in Orlando. You may or may
15 not know if these people actually ate the same food
16 or if it was even a non-food related reason that
17 they got sick.

18 So the whole business of epidimiological
19 science to establish what actually contributed to
20 illness is improving. So we expect over the next
21 few years to see an increase in the incidence of
22 reports and we then want to have a system at the
23 Federal and local level that can deal with that
24 appropriately.

25 In addition to the surveillance system, we

1 have coordination and we have formed and tomorrow
2 there will be an event, I think the Vice-President
3 will be announcing, a foreign food illness outbreak
4 response coordination group, MOU, between the
5 States and the Federal governments that we would
6 have a formal mechanism on following up on
7 foodborne illness outbreaks.

8 And again, the Food Safety Initiative has two
9 roles, one, to reduce to the greatest extent
10 possible the foodborne illnesses associated with
11 foods, and secondly, to improve the infrastructure
12 at the Federal, State and local levels to deal with
13 those outbreaks and illnesses and to force the MOU
14 and the surveillance system that CDC is
15 establishing are two activities and initiatives
16 that try to fulfill the improvement of that
17 infrastructure.

18 In addition we are pursuing research and risk
19 assessment. Again, there is much we do not know
20 about microcontaminants in food. By and large the
21 science is well established in the clinical
22 setting, in the hospital setting, taking human
23 fluid and assessing those for those microorganisms,
24 but there is very little science, methods, how to
25 sample on foods. It's very difficult. Each food

1 is a different environment for that microorganism.
2 Some microorganisms flourish in certain foods,
3 others do not. And it's very difficult to make
4 extrapolations or too broad generalizations on
5 that. So there are ambitious research programs,
6 both within the Department of Agriculture, Food and
7 Drug Administration and other Federal agencies,
8 likewise, and industry, to answer many of the
9 fundamental questions so that we can provide
10 specific guidance where appropriate.

11 Education, we have entered into a public,
12 private partnership with a number of industry
13 members, consumer groups and Federal agencies to
14 promote the Fight-Bac campaign. Fight-Bac is an
15 attempt to educate retailers, food handlers and
16 consumers that they play a large role in providing
17 safe food at the table. We are not only focusing
18 at the farm level, we are focusing at every stage
19 from farm to table, and the delivering of food to
20 the U.S. consumer in getting the message across
21 that each level plays an important part in ensuring
22 that food is safe.

23 Hence, with education we are trying certain
24 educational messages, we are conducting research in
25 that regard to see how consumers react. We have

1 tried that with seafood, about seafood toxins.
2 We've tried that about other foods. Some time
3 people just turn off, they won't even pay attention
4 to it or that message will not change their
5 behavior, and we are trying to learn what will
6 change their behavior so they are more aware and
7 then make a conscious decision rather than an
8 unconscious decision as to whether they are going
9 to have a certain behavior or not.

10 And lastly is inspections, under inspections
11 we hope to increase inspections as we learn more
12 about how to do those inspections. What is
13 different within the Food Safety Initiative than we
14 have in others? We are moving from a chemical
15 hazard to a micro hazard framework. In chemical
16 hazards one can be relatively assured as you sample
17 a food product, if you sample ten percent or two
18 percent, you have a general understanding of what's
19 in that particular lot. With microbe contamination
20 you do you not have that certainty. In the case of
21 Cyclospora we know that as few as a few berries
22 made people ill. Well, if a few berries made
23 people ill, how can we sample all the raspberries
24 from whatever source so that we can assure that
25 there is no Cyclospora.

1 Likewise, the research is not there for us to
2 fully recover that parasite from that food product.
3 Hence, we need to do additional research so that
4 our investigations, if we do get additional
5 resources to conduct more, actually have a basis on
6 what to look for. Currently we look at sanitation
7 practices, but in large parts microorganisms are
8 not necessarily visible. You do not know when a
9 food product may or may not be contaminated, hence
10 the science is very important for us to proceed in
11 an appropriate and deliberate and informed manner.

12 Within the Food Safety Initiative, Food and
13 Drug Administration, Department of Agriculture and
14 others are going on on many -- going along on many
15 different fronts. We are trying to make each
16 contributor to the farm, the table, continuum aware
17 of microhazards and how they must deal with them.
18 And it's very important that we have this awareness
19 and we get this science as soon as possible to
20 respond to these foodborne illness outbreaks.

21 So by and large I believe the Food Safety
22 Initiative really is trying to change culture, it's
23 trying to change understanding of the food system,
24 it's trying to make people more responsible for
25 their putting products on their table. Consumers

1 also have a responsibility, it's not simply with
2 the producers. Consumers must take care as they
3 put food on their table and that's what the
4 Fight-Bac campaign is about. In order to you must
5 keep foods chilled, if they are to be chilled, must
6 separate so you don't cross-contaminate and
7 consumers, retailers and others need to be aware of
8 that.

9 So the message I can leave with you is we are
10 not simply focusing on the farm level within the
11 Food Safety Initiative and the produce initiative,
12 we are trying to target each and every level and we
13 are trying to get the appropriate messages to those
14 constituents so that there will be a difference.
15 Thank you.

16 MS. PEAL: If I may, and I've calmed down,
17 sir. Mr. Carson, why don't you as the FDA have the
18 same authority to recall bad products as the USDA
19 does with meat and poultry?

20 MR. CARSON: The point raised by Ms. Peal was
21 why don't we have the same authority as the U.S.
22 Department of Agriculture on recalling products. I
23 think you'll be surprised to know that Secretary
24 Glickman has proposed recall authority for the
25 Department of Agriculture because he doesn't have

1 the full extent that he thought he had either.

2 Neither agency has full recall authority. I
3 think Mr. Tolen can probably talk about cases here
4 in Florida of how we actually do it, but by and
5 large we rely on industry to recall that product
6 because we do not have the legislative authority to
7 require Congress to give us that legislative
8 authority to do that. We have in the past proposed
9 a number of legislative remedies to this, to date
10 we have not received that authority. So by and
11 large right now it is a handshake between the
12 Federal government and industry when we find a
13 problem, and by and large industry does respond to
14 recalling products, but there are -- at points in
15 time there are difficulties, and again much of that
16 has to do and we tried to address that in our
17 traceback system, that not all product is properly
18 marked so that it can all be recovered easily.

19 In the case of fresh produce you know there's
20 a large amount of repacking and commingling of
21 products, raspberries are little raspberries.
22 You've seen stickers on apples, but it's not easy
23 to put stickers on raspberries and things like
24 that. So there are some institutional difficulties
25 in doing that, but nonetheless we would recommend

1 that we do so in our guide that industry take
2 appropriate measures so that we can retrieve or
3 locate their products when we find that there's a
4 problem and recall it.

5 But the short answer to your question is we do
6 not have the legislative authority to do so.

7 MR. DERSTINE: I'm Wayne Derstine, Florida
8 Department of Agriculture and Consumer Services. I
9 appreciate the opportunity to address you as far as
10 enhancing food safety through our cooperative
11 programs. The safety of food supply continues to
12 command public interest. As you can see today the
13 issues are many and they are varied, included but
14 not limited to environmental contaminants,
15 pesticide residues and, of course, microbial
16 contamination. New situations and issues prompt
17 discussions about the scientific evidence, public
18 perception, necessary control measures and
19 appropriate claims and labelling actions.

20 The interplay of legislative, regulatory
21 scientific, social and political forces is evident
22 with every issue that comes before us as far as
23 food safety. Certainly government plays a major
24 role in guarding the safety of the food supply
25 through a variety of laws, regulations, standards,

1 guidelines and control measures.

2 In addition, the food industry plays a
3 critical role in helping to control food hazards.
4 Our levels of industry adopt quality assurance and
5 quality control programs that reflect industry's
6 standards, company standards, consumer expectations
7 and government regulations. In addition, consumers
8 have a responsibility for food safety.

9 Everyday a consumer, and I know each one of
10 you makes decisions for your family to ensure the
11 safety of each one of your family members,
12 therefore, we can say that it's certainly a
13 cooperative effort. It's a partnership with
14 consumers, with industry and with government to
15 support food safety.

16 As far as the State of Florida, the Department
17 of Agriculture, some of your perspective as we see
18 them from the food safety issue, we have certainly
19 seen an increase consumer awareness of food
20 safety. That is due to consumer education, the
21 media and various other sources. We certainly
22 encourage the labelling, the coding, the tagging of
23 products to help us in the traceback that's already
24 been mentioned. We go through a lot in trying to
25 ensure that when we have a foodborne illness

1 MR. GOMEZ: But they are also coded.

2 MS. GILLEN: Just on the point of traceback
3 and how important it is, what efforts are being
4 done by USDA to be sure that produce is in
5 correctly labelled boxes. We found many occasions
6 here where produce was put in boxes and said USDA
7 inspected, and one example is carrots used being
8 poured from a bag that said produce of Mexico, does
9 that bother you?

10 MS. NIELLA-BROWN: Michelle, excuse me, let's
11 try for now to keep the questions to the question
12 and answer period and limit it to the draft guide,
13 which is the purpose of this meeting, and I'm sure
14 if you want they will be happy to do one on one
15 interviews with you later on.

16 MS. GILLEN: That's fine, but I'll just finish
17 up with the gentleman now. It's just in the larger
18 picture I have formally requested interviews with
19 the government for six months and not been given
20 those interviews, so forgive me for wanting to ask
21 those questions today.

22 MS. NIELLA-BROWN: I understand but --

23 MS. GILLEN: I was not allowed to ask either
24 the USDA or FDA for interviews.

25 MS. NIELLA-BROWN: What we are trying to do

1 today is gather input from the audience.

2 MS. GILLEN: I understand, but let me just
3 close on that one point, sir. Is that acceptable,
4 the fact that we have found examples of produce
5 being put in boxes and saying USDA inspected when
6 indeed the produce came right out of packages that
7 said produce of Mexico?

8 MR. GOMEZ: I'm sure if it was put in those
9 boxes that said USDA inspected, and if something
10 was put in those boxes, it was either USDA
11 inspected or it's illegal.

12 MS. GILLEN: What I'm saying is, it certainly
13 appears to be illegal, does that concern you and
14 what effort --

15 MR. GOMEZ: Yes, it does definitely.

16 MS. GILLEN: What efforts can be done, will
17 be done to correct that?

18 MR. GOMEZ: I think Lou addressed some of that
19 before. Our resources are not up to what perhaps
20 we think they ought to be. We are doing the best
21 we can with what we have. We have requested
22 additional inspections and so on and so forth.
23 That's my answer, we are doing the best we can with
24 what we have at this point, and we are concerned.
25 That is a certain, sure.

1 MS. NIELLA-BROWN: We now need to move on with
2 the agenda, and I believe Lloyd Harbert will be
3 addressing the audience at this time.

4 MR. HARBERT: I was hoping we were going to
5 break for lunch, but I guess I don't get off that
6 easy. Hi, I'm Lloyd Harbert, I'm with the
7 Department of Agriculture, Foreign Agriculture
8 Service and I work in an area called International
9 Trade Policy, so essentially my office is involved
10 in the foreign side of the trade component of the
11 Food Safety Initiative. I just thought for some of
12 you that weren't aware of how the Foreign Ag
13 Service is structured. Essentially they have 631
14 personnel in Washington, D.C., about 110 foreign
15 service officers in overseas covering 133
16 countries, plus an addition 12 buy/trade offices
17 that are involved in promoting food products in
18 foreign markets. Trade offices principally being
19 some of your larger commercial markets.

20 Essentially the mission FAS has is it's
21 involved primarily in trade promotion, also
22 providing market intelligence and also technical
23 assistance and training to foreign government. And
24 the reason I wanted to point that out is so you get
25 a sense of why we've been working with the Food and

1 Drug Administration in putting in place the
2 President's Food Safety Initiative, particularly as
3 it goes in regard to produce, the produce
4 initiative. I think-- the first point I want to
5 stress is it really is a government effort across
6 the government, it's not just within one
7 department, it isn't just Health and Human
8 Services, it's not even just the Department of
9 Agriculture and Health and Human Services, it's
10 involving State departments and others in the
11 formulation of good ag practices documents. For
12 example, we've got those out to all the foreign
13 government embassies and also to our embassies in
14 the field to get comments back on those specific
15 practices.

16 I think the other thing that I wanted to
17 emphasize, too, is that our trade partners
18 particularly need to see the President's Food
19 Safety Initiative and particularly the initiative
20 of our produce as a public health initiative, not a
21 trade initiative. I think that was particularly
22 worrisome, I think, for us in a trade agency at the
23 beginning of this, because a lot people saw it as a
24 way to shut down imports into this country, and
25 that could come back to bite us. Just as much as

1 our consumers like to think we have the safest food
2 supply in the world, I can tell you other countries
3 like to think their food supply is the safest in
4 the world. So we'd have to have a balance as we
5 move forward with that.

6 I wanted to show just a couple of quick
7 overheads because I think it draws attention where
8 public perceptions are in terms of food attributes
9 and what is a serious hazard. We've actually done
10 this more in regard to an issue we are addressing
11 now on biotechnology, not necessarily microbial
12 contamination, but as you can see, it depends on
13 consumer's perceptions, particularly microbial
14 contamination now even exceeds pesticide residue.
15 Now that may be because popular press and media
16 picked this up, but it clearly is on the minds of
17 the American consumer and also on the minds of
18 European consumers in terms of serious hazards,
19 bacterial contamination, pesticides and some of the
20 other issues. But I just wanted to draw quick
21 attention to that because I think just, again, you
22 have to look at these issues, not just in the
23 context of the U.S., but also globally.

24 The next point I wanted to make here is, FAS
25 is currently working with the FDA trying to define

1 our international efforts. At presently we are
2 currently meeting on a bi-weekly basis, every
3 Thursday, and also to design exactly how we can go
4 about building the scientific basis that Lou drew
5 attention to. We have a long history of working on
6 pesticide type issues overseas, whenever there is
7 decontamination actions and we need to do follow up
8 with foreign governments, we -- our field officers
9 will work in cooperation with FDA officers when
10 they would actually physically come into a country
11 and work with the host country government. We
12 don't like to use our foreign service officers as
13 sort of compliance or enforcement officers because
14 they are working in embassies trying to promote
15 agricultural trade in general, not specific issues.

16 Now, the programs that we are currently
17 working with, when we try to reach out to foreign
18 governments and work with them, the first one is
19 the Cochran Fellowship Program, and they are
20 essential bringing in foreign government officials
21 into the U.S. to get specific training. Right now
22 we are designing some specific training modules
23 around food safety, around microbial contaminants.
24 In the past we've done similar things in the area
25 of toxicides. We also have an emerging market

1 program that provides technical assistance to
2 developing countries, and finally we have a
3 scientific cooperation program which funds
4 collaborative research projects and scientific
5 exchanges. And that's the areas that we are going
6 to be concentrating on, particularly as we try to
7 look at microbials and get at some of the issues
8 that Lou mentioned where we just don't have good
9 information at present, not just here domestically
10 but internationally.

11 As we look forward, right now we are looking
12 basically in four general areas in the
13 international area. First is increasing awareness
14 of how our own food net surveillance system is
15 working, because one thing that I think was drawn
16 attention to by some of earlier speakers, now that
17 we have expanded surveillance capacity we are going
18 to have more outbreaks reported. That's not an
19 indication of the food supply in the United States
20 and the safety of this food supply is in jeopardy
21 or deteriorating, but the problem is that that
22 information gets picked up in the media and
23 publicized, the foreign governments keep coming
24 back into my office and saying, well, can you give
25 a guarantee that your products are safe or as we do

1 recalls here in the United States, the first
2 question the foreign governments ask us is, did you
3 ship any products to our market? And so we are
4 improving the systems we have and transferring that
5 information on a very timely basis back and forth
6 to governments.

7 The other thing that is secondary that we are
8 working on is improving our risk assessment methods
9 for microbial contamination, and the reason we are
10 focusing on that particular area, we've had a lot
11 of experience looking at microbial contamination on
12 red meat, seafood and those areas, but not so much
13 in the area of produce. It was only very recently
14 that you'd even get trade associations or producers
15 or other groups to acknowledged that possibly
16 microbial contaminants could appear on produce
17 because we, in fact, hadn't had any tracebacks that
18 really drew attention to that as an imperative
19 concern. That's only been fairly recent in time
20 that we'd had this CDC information pointing out
21 that that is a potential area of concern.

22 The third area of which I touched on briefly
23 is just improve the risk communication. I think
24 that, again, that's that issue of as we report more
25 foodborne illness outbreaks, how we communicate

1 that internationally. And then finally I think in
2 the facilitation of the development of
3 international standards or guidelines, one of the
4 key components in facilitating trade is having
5 international standards that we all adhere to.
6 Right now there are not good international
7 standards developed around microbial contamination
8 of trade -- international trade and food sups. And
9 why that becomes a concern is it gets some of the
10 very specific questions that we raised here a
11 little bit earlier, is that two percent inspection
12 rate good enough? How about twenty percent? Why
13 not fifty percent? If you really want to stop
14 trade you can take the greater approach and say 100
15 percent inspection, and we had to get into rather
16 lengthy discussions about that. Okay, what is the
17 specific hazard? What is the particular microbial
18 problem that you want us to address here? Why do
19 you think 100 percent inspection rate is justified.

20 Now, particularly they can adopt the 100
21 percent inspection rate for a period of time and
22 still not find any hazard. Then you have to make
23 the argument back 100 percent isn't justified,
24 maybe you should lower that inspection rate. So
25 that's the area that we are working with the Food

1 and Drug Administration and other agencies to help
2 develop that international agenda. I know that
3 it's 12:15, but we are probably going to try to
4 have just a few questions before we break for
5 lunch. I just want to thank you for your attention
6 and I hope that kind of broadened the scope. Thank
7 you.

8 MR. TOLEN: I'm going to talk about
9 tracebacks, but let me give you a choice. I need
10 about maybe five or seven minutes to do that, you
11 can request if you need a break now, go to lunch
12 and when we come back go ahead and do that or go
13 through that area and break for lunch, what's your
14 preference?

15 MS. GILLEN: Continue.

16 MR. TOLEN: Continue, okay. Let's talk about
17 tracebacks first. I'd like to do that by telling
18 you a little story, perhaps an analogy. All the
19 names are made up to protect the innocent and the
20 guilty. This is a story about a gentleman down in
21 Peru, his name is Peter. He's a goat herder. He
22 has about 20 goats, a broken down truck and he buys
23 and sells goats on his five acre farm. But to make
24 a little additional money he also has 100 pear
25 trees, so Peter raises pears in Peru and he picks

1 these pears, puts them in his trunk and takes them
2 to Paul. Paul cartons these pears up and he ships
3 them to Miami.

4 Mary in Miami runs a kitchen and manufactures
5 airline meals, and she buys a pallet load of Paul's
6 pears from Peru and she makes a mixed fruit salad,
7 which she then marries with a chicken salad and
8 puts it on a platter. She also makes ham
9 sandwiches, which have garden salad and she puts
10 them on the platter and she sells them to American
11 Airlines, which puts them an a flight from Miami to
12 New York.

13 On that night are 350 people, about half of
14 them eat the ham sandwich with the garden salad,
15 the other half have the chicken salad with the
16 fruit salad. Half the people get sick diarrhea and
17 vomiting. So this is reported to a variety of
18 Federal, State agencies and they conduct an
19 epidimiological investigation as to what caused the
20 problem. In that investigation they determine that
21 the people who got sick all ate the chicken salad
22 with the fruit salad platter and those who ate the
23 ham sandwich with the garden salad did not get
24 sick, so that helps traceback the information as to
25 what may have caused this problem, which they want

1 to do not only to prevent the problem but what else
2 may be out there that may be contaminated to cause
3 this illness.

4 Eventually they traced those meals back to
5 Mary's kitchen in Miami, and they go in and collect
6 some samples there of the variety of ingredients of
7 the meal of the manufacturer. The source of the
8 suspicion is the chicken salad because chicken is a
9 hazardous substance in its own right, but lo and
10 behold they don't find any problem with the chicken
11 and when they go back to the kitchen they find Mary
12 still has a pallet of pears from Paul in Peru, and
13 they take a sample of that and lo and behold find
14 salmonella on some of those pears and the same
15 depreciation is in the fecal material and the blood
16 from the patients who were hospitalized from the
17 illness.

18 Now, if they had not found salmonella in the
19 pears, the assumption could have been made perhaps
20 that somebody in Mary's kitchen could have been
21 ill, could have had a boil, could have contaminated
22 fruit salad that was manufactured, but since they
23 found the salmonella in the pears the assumption
24 now is we trace this product back to Peru from
25 which it came.

1 We know that the pears came from Paul, who
2 cartoned them up, but unfortunately there were no
3 codes on the pears from Paul, so we don't know
4 which of the suppliers contributed those to Paul,
5 those pears to Paul. But if it had been properly
6 coded so that Paul could trace those pears back to
7 Peter who picked those pears off of the ground
8 where his goats had gone to the bathroom and put
9 them in his truck, which he hadn't cleaned since
10 the last time he transported goats to the market,
11 we might have been able to trace that back to the
12 actual source of contamination.

13 The point I'm going to make is that the
14 regulations, there's about three or four pages
15 devoted to tracebacks and the importance of
16 properly identifying and marketing. You mentioned,
17 Michelle, orange juice and coding. Theoretically,
18 although there's a legal requirement to do so, at
19 least in the FDA regulations, you'll see usually on
20 most manufactured products that you buy in a
21 package in a supermarket a series of codes and most
22 manufacturers will be able to interpret that code
23 and tell you the date it was made, the manufacturer
24 plant, the line it was made on, the shift it was
25 made on, so if we find a problem with that orange

1 juice that you mentioned and indeed it is
2 contaminated, the manufacturer says, oh, find out
3 what the problem was, they can say that was made on
4 the A shift using this source of ingredients and
5 that went to these locations. We need to not only
6 solve the problem when you identify it, but we need
7 to go back and recall the merchandise that may
8 still be out there making others ill. That's the
9 whole point of tracebacks.

10 If you don't have a traceback system in place
11 and you don't code it -- now what happened in the
12 case of the pears of Peru, we know that we had a
13 problem with Peruvian pears but only from one
14 shipper, so the safe thing to do is say, we don't
15 want to ship any pears, we don't want to receive
16 any pears from Peru and we indict the entire
17 Peruvian pear industry because we can't trace that
18 back to the specific source.

19 So one of the advantages to a shipper is to
20 make sure they know where that came from and it's
21 also an advantage to the industry from which those
22 products are shipped, because they are able to
23 pinpoint the actual source and not indict the
24 entirely industry because we can't actively figure
25 out where that came from. So the whole point of

1 the traceback is to put numbers on there, as you
2 heard Martha Roberts mention this morning, some
3 people can even code this back so that they can
4 trace that back to the individual shipper. I'm
5 sorry, individual picker. The picker may have had
6 sores on their hands, may have a cut that got
7 infected, so every item that they touched is a
8 source of contamination. And if that product gets
9 washed somewhere they multiply that contamination
10 and everything that goes through the same wash
11 water picks up that pathogen.

12 So it behooves us when we see that in the
13 guidelines we've set up a traceback system which
14 allows you as the manufacturer, you as the grower,
15 you as the producer and us as the Federal agency to
16 be able to find the source of that contamination
17 and take steps to not only fix that for future use
18 but also and more importantly to make sure that any
19 other product from the same source on the market
20 may be removed so that we don't continue to spread
21 the illness or the infection that may be causing
22 the problem.

23 Take a close look at those three or four pages
24 of the guidelines there and it's appropriate for
25 your operation to consider that, and admittedly

1 it's different for every kind of operation or may
2 be. If you pick potatoes and they go through some
3 wash water and are sorted by size, then my potatoes
4 get in a whole bunch of different cartons. If I'm
5 a picker of raspberries, you put the raspberries in
6 a carton, that carton is shipped and it's only my
7 hand who touched that so you need to look at in
8 light of the kind of operation you have and how
9 things might be handled.

10 If you have any written questions give them to
11 Frank. Let me ask this question so everybody
12 understands what it is. The question, what
13 measures can the initiative introduce to make sure
14 good agricultural practices are actually followed
15 by foreign producers and just not simply ignored?
16 Would farm certification/inspections randomly
17 performed fall into this picture?

18 Lloyd, do you want to answer that question?

19 MR. HARBERT: That's a good question. As I
20 think it's been suggested here the guidance is a
21 voluntary guidance, it's not mandatory. However,
22 having said that, I can tell you all the suppliers
23 of fruits and vegetables to the United States are
24 very interested in this initiative. We've received
25 numerous requests for any kind of direct

1 involvement either having our teams come out and
2 work with them or with their producer, grower
3 groups and actually taking a hard look at good
4 agricultural practices documents.

5 We've had several countries approach us,
6 Mexico being one, but several additional countries
7 throughout Latin America, expressing desire to be
8 involved in any pilot surveys that we might do of
9 field surveys with production practices. So I
10 guess my point would be, I don't think, you know,
11 this is such an important area for countries that
12 they are going to simply ignore the practices.
13 They do not want to see their exports in any way
14 have a food safety or a foodborne illness outbreak
15 being traced back to them.

16 One of the things that came out is, I think we
17 recently had some meetings with the Center of
18 Disease Control and CDC view collaboration
19 historically has been when they are in the midst of
20 doing traceback, that's when they collaborate with
21 foreign governments and increasingly the foreign
22 governments are saying, can you collaborate with us
23 before the fact. Now, let's make sure how we can
24 improve our own system, surveillance systems for
25 foodborne illness outbreaks in other countries.

1 I think it's an evolving process and I think
2 the good agricultural practice document is a work
3 in progress, and it's becoming an educational view
4 from not only here in United States, but
5 internationally, and at some point in time that
6 good agricultural practice document may find its
7 way and become an international guideline.

8 MR. TOLEN: As we move more and more into a
9 global marketplace, there's more and more concerns
10 on countries who have a big chunk of the American
11 market to make sure that the produce coming from
12 their countries meet our requirements. It's too
13 much money involved not to have been interested in
14 that activity.

15 MS. GILLEN: In terms of dealing with foreign
16 countries, has there -- has any of your staff per
17 se ever visited any of the farms, specifically in
18 Mexico, and specifically investigated concerns
19 regarding questionable sanitation, lack of
20 handwashing facilities and bathrooms?

21 MR. TOLEN: Did everyone else in the room hear
22 that question?

23 MS. GILLEN: Given your responsibility on the
24 foreign area, you are saying in countries such as
25 Mexico actually are proactive to work with the

1 United States regarding standards of food safety,
2 has anyone on your staff or do you have any
3 information brought back independently other than
4 taking their word for it? For example, I myself
5 visited there and went to many farms where there
6 were actually no handwashing facilities, very few
7 toilets if, any on, some farms. Is that
8 information that you have been able to investigate
9 or concerned about or have at all independently,
10 you know, looked at or is that something totally
11 off the radar screen?

12 MR. HARBERT: For my specific agency within
13 the Department of Agriculture Foreign Ag Service,
14 we do not have a public health and safety role, but
15 what we are is the principal representative of the
16 Secretary of Agriculture in that country, and so
17 for that role we have interactions like the Food
18 Safety Inspection Service on red meat and poultry.

19 In addition, we've interfaced with the Food
20 and Drug Administration and their staff to come
21 down to arrange field visits. But our staff per
22 se, because we are economists, scandalous speaking,
23 and the last thing we want is an economist going
24 out and trying to talk about microbial
25 contamination, I can tell you that for a fact.

1 We are strengthening that effort, that's why I
2 was trying to draw attention to the issue on
3 pesticides. That was an area that there was
4 involvement, but our officers physically did not
5 get directly involved. What they do is arrange for
6 incountry visits, identify which were the key
7 government officials to work with.

8 MR. GILLEN: But USDA, unlike the meat and
9 poultry, who are not responsible for the food
10 safety element regarding --

11 MR. HARBERT: Right, we draw on the regulatory
12 agencies back in the U.S. and then facilitate
13 carrying out their function in that country, we
14 don't but have that regulatory authority.

15 MS. GILLEN: That regulatory authority does
16 belong to the Food and Drug. Mr. Tolen, maybe you
17 can enlighten me on something that I've been trying
18 to get to the bottom of, and the guidelines make
19 some reference to difficulty in some testing. Tell
20 us specifically when an FDA inspectors go to
21 facilities where foreign produce has come in, give
22 us the list of exactly when the inspection does
23 take place. What they are inspecting for?

24 MR. TOLEN: Is your question in reference to
25 the foreign firms or when the produce hits the U.S.

1 shores?

2 MR. GILLEN: Both.

3 MR. TOLEN: Let me address the foreign firms
4 first, because we have no authority, as we speak,
5 to be in foreign countries inspecting foreign
6 firms.

7 MS. GILLEN: I'm talking about once it hits
8 the United States, not before that.

9 MR. TOLEN: Let's take Miami, specifically,
10 because this is a ideal location to talk about
11 that. In Miami we get some 800 entries or
12 thereabouts a day of products that are regulated by
13 the Food and Drug Administration. We have about 20
14 people to collect samples and look at these
15 entries, so we have to do as I call it triage. We
16 have to make conscious decisions about the products
17 that we look at and microbiology problems in
18 produce is just one of the many concerns we have
19 about the food supply, we are concerned about
20 pesticides in foreign produce, we are concerned
21 about heavy metals in seafood, we are concerned
22 about decomposition of seafood. So there are
23 thousands of combinations of products and problems
24 that need to be considered and obviously you can't
25 look at everything for every possible contaminant,

1 so we have to make some decisions about what we
2 would look at and only a small number of those 800
3 entries per day are selected for further
4 consideration.

5 When that selection is made, and in part
6 that's done by computer based on prior the history
7 of a particular product, prior history of that
8 particular country, even prior history of that
9 particular importer, one of our folks will go to
10 that importer and he will collect a physical sample
11 of that merchandise. Let's say it's a product for
12 pesticides --

13 MS. GILLEN: Let's not talk about pesticides
14 since the guidelines don't address pesticide
15 problems, let's deal with --

16 MR. TOLEN: We have a few guidelines for
17 microbiological hazards in produce.

18 MS. GILLEN: That's what I'm trying to get at,
19 just tell us what, if any, micro -- I can't
20 pronounce it as well as you do, what micro --

21 MR. TOLEN: If we find a disease causing
22 pathogen in a product, then we would normally take
23 a, we call it a detention action, we would detain
24 it, but let me give you --

25 MS. GILLEN: Here's just my question, what are

1 the pathogens the FDA inspectors collect samples to
2 test for, what are we actually testing for in this
3 country?

4 MR. TOLEN: That's going to depend on what
5 the product is.

6 MS. GILLEN: But give me the whole -- let's
7 start this way. Do we test for E-coli?

8 MR. TOLEN: We test for E-coli in products
9 where that may be a problem.

10 MS. GILLEN: But what you are saying is if FDA
11 inspectors might suspect for some reason a product
12 is tainted with E-coli, they will -- they do send
13 samples to laboratories to confirm or --

14 MR. TOLEN: Yes. You used the term if we
15 suspect, if we had reason to be concerned about a
16 particular product, then obviously we would collect
17 it for that particular reason. Our laboratory
18 happens to be in Atlanta, so that sample would then
19 be shipped to Atlanta for analysis and a decision
20 be made on whether that product will get into this
21 country or not based on the results of that
22 analytical evidence.

23 MR. GILLEN: Now --

24 MR. TOLEN: Let me say this, it's important
25 for me to say this. In many cases the

1 microbiological testing may take two weeks.

2 MS. GILLEN: Right.

3 MR. TOLEN: So are we supposed to hold up the
4 entry of all these products for weeks on end with a
5 perishable limit while we run all these tests, and
6 the answer is generally, unless we have a strong
7 reason to suspect that that particular lot is
8 contaminated, in all likelihood we would not hold
9 perishable products for more than a day pending the
10 analytical outcome. So we are trying to balance
11 the movement of cargo with our consumer protection
12 mission.

13 MS. GILLEN: Does FDA test for Cyclospora?

14 MR. TOLEN: We, and Lou may be able to answer
15 this better than I can, we have a method for
16 Cyclospora, but as you heard earlier at this point
17 we have not been able to find any Cyclospora. We
18 suspect it's there because we see evidence that
19 epidimiologically we are tracing back to some
20 products. I'm not a laboratory person, I'm not
21 sure how good that methodology is, but we continue
22 to still look for Cyclospora organisms in this
23 product which we suspect epidimiologically that
24 they may exist.

25 MS. GILLEN: One last question. Do you

1 believe that -- do you agree with the policy that
2 allows distributors and manufacturers to choose
3 their own laboratories for FDA testing? There was
4 criticism of that in the GAO report, which actually
5 made reference to some cases where bogus product
6 was actually taken to the labs? What's your
7 opinion on that? Do you think that should be
8 changed?

9 MR. TOLEN: Let me answer that last question
10 because we have to break for lunch.

11 I think that you asked the question
12 incorrectly. Your question was about allowing
13 importers to choose their FDA laboratories?

14 MS. GILLEN: No. No. No. Individuals --

15 MR. TOLEN: Private laboratory?

16 MS. GILLEN: Exactly.

17 MR. TOLEN: Here's the choices we have to
18 make--

19 MS. GILLEN: Just tell me, do you agree with
20 the policy or not?

21 MR. TOLEN: Let me ask you this as a consumer,
22 would you prefer to have the same test by a private
23 laboratory of the importer's choice or not at all?
24 Because that's the question you are faced with.

25 MS. GILLEN: Why?

1 MR. TOLEN: Because there's simply not enough
2 resources. The Federal government, particularly
3 FDA, to sample every product, for every attribute
4 in FDA facilities.

5 MS. GILLEN: So you are saying the choice for
6 the consumers today is either allow the
7 manufacturers or distributors to pick their own lab
8 or not get anything at all?

9 MR. TOLEN: What I'm saying is that in
10 addition to the analysis that we perform in FDA
11 laboratories, we also have programs which say to
12 the importer you may opt to use a private
13 laboratory of your choice to analyze in lieu of
14 ours. The point being here is that more samples
15 getting analyzed in favor of the consumer than it
16 would be if we just used our own facility, I think
17 that's the bottom line.

18 Now, it's true that on occasion there are
19 situations where that privilege is abused and we
20 deal with that when we find it, but the bottom line
21 is, you as a consumer, if we can sample five
22 percent and test it or we could have 35 percent
23 tested in a combination of Federal and private
24 facilities, which offers the better protection for
25 the consumer?

1 It's our conclusion that by allowing some of
2 this stuff to be tested by private laboratories
3 that we are getting a better product on the
4 market. We have had many instances where private
5 laboratories have found things on the product and
6 we've been able to take an action against it, which
7 we would not have found on our own, since we didn't
8 have the resources to examine that large a number
9 of units.

10 So the bottom line answer to the question is
11 yes, I believe in that and yes, there are
12 occasional abuses of it, but the bottom line is I
13 think the consumer is better protected with a
14 program of that nature.

15 I'm sorry, we are way beyond 12:30. Let's
16 take a lunch break. We are going to short-circuit
17 it just a few minutes. If you can be back at 2:00
18 then we'll take more questions and then continue
19 with rest of the program. Again, I apologize for
20 all this. We want to make sure that you as
21 industry representatives have an opportunity to
22 have input here for the process which we are here
23 for. So again, if you have questions you would
24 like to come to the podium with, after lunch please
25 feel free. If you have questions you'd like to

1 write down, by all means.

2 Thank you, we hope to see you back after lunch
3 to get your feedback and input to this process.

4 (Thereupon a lunch break was taken in the
5 proceedings, after which the proceedings
6 continued as follows:)

7 MR. TOLEN: Take your seats, we'll try and
8 reconvene, please. Thank you all for coming back.
9 Sometimes we have these meetings and come back from
10 lunch and no one is here, so we appreciate you
11 coming back to participate in the second half of
12 the program.

13 Before I turn the program back over to Estela
14 to introduce our first afternoon speaker, let me
15 ask whether there are anymore of these forms that
16 you might have filled out during lunch break that
17 we should ask those questions and get those
18 addressed. I'm surprised you are so quiet, this is
19 your opportunity. The press hasn't come back from
20 lunch. So it's an opportunity here for somebody
21 else other than CBS. Are there any questions from
22 the floor?

23 MS. NIELLA-BROWN: I also wanted to make the
24 clarification if some of you do not feel
25 comfortable enough stating your question or writing

1 your question in English and you want to do it in
2 Spanish, feel free to do so and we will translate
3 the question and the answer for you.

4 MR. TOLEN: Okay. Let me turn the program
5 back over the Estela to introduce the first speaker
6 of this afternoon.

7 MS. NIELLA-BROWN: Okay. The next session on
8 the agenda is the guidance document presentation
9 and working session, and Dr. Michelle Smith will be
10 in charge of this next session. Dr. Smith is an
11 interdisciplinary scientist at the Food and Drug
12 Administration, Center for Food Safety and Bad
13 Nutrition. She's part of the Food Safety
14 Initiative team and she's the author of the guide
15 to minimize Microbial Food Safety Hazards for Fresh
16 Foods and Vegetables. So take advantage of
17 Michelle this afternoon and ask as many questions
18 as possible.

19 MS. SMITH: Thank you. It's going take me
20 just a minute the get set up here.

21 MS. NIELLA-BROWN: Michelle is also going to
22 show the slides in both English and Spanish.

23 MS. SMITH: Estela, if you can turn on both
24 those slides projectors. I took a few notes this
25 morning during other people's presentations just to

1 remind me of some of the points that I'd like to
2 make in way of introductory remarks.

3 One of the points is that Doug Tolen and a
4 number of other people said that this is your
5 opportunity to let us know if you have any problems
6 with the guidance document, I'd like to expand on
7 that. If there's anything you like about it, feel
8 free to tell us also.

9 To put this document in perspective, it is a
10 guidance document and there are a number of
11 significant gaps in our knowledge as to pathogen
12 survival in the field and on fresh produce. And
13 there was some discussion or concern, I think,
14 about the agencies just continuously studying and
15 studying and studying and not taking action, and
16 I'd like to say at this point that that's one of
17 the reasons that this is guidance.

18 The purpose of this document is to increase
19 awareness about potential sources of contamination
20 for fresh produce and to try and encourage the kind
21 of action that may minimize the hazards that are
22 possible in the field in packinghouse environments.
23 I consider this a very positive step within
24 conducting a number of tours of farming and
25 packinghouse operations. Everything that I've seen

1 so far, people have already taken their own steps
2 and they are making very conscious efforts to make
3 their operations as good as possible.

4 At the same time some of the comments that we
5 got on the working draft said thank you very much
6 for putting this out there. There are some things
7 in here that we hadn't thought about, and so what
8 we are trying to do, much of this may have been
9 common sense that people are already following but
10 also to increase awareness of all of the potential
11 sources of contamination and maybe get people to
12 look a little harder at their operations and see
13 what factors they may have control over that they
14 hadn't addressed yet.

15 The way that I was thinking about handling
16 this, this afternoon's working session, is to go
17 through the document and present some of the types
18 of recommendations that we've provided on a section
19 by section basis, and pause at the end of each of
20 those sections for any comments and questions that
21 you may have on those particular topics before
22 moving on to the next session. What I'm trying to
23 do now is start in the same place.

24 In the guidance document, based on current
25 sound science and knowledge of FDA, USDA and a wide

1 range of technical experts in other Federal
2 agencies and at the State level, we have identified
3 common potential sources of contamination in the
4 agricultural and processing or packinghouse
5 environments. Those areas are water, manure or
6 biosolids, worker hygiene, field facility
7 sanitation, and transportation.

8 The first area that we look at is water. The
9 source and quality of water dictates the potential
10 for pathogenic contamination, and water is a
11 concern in two regards. First, it's a direct
12 source of contamination if pathogens are present in
13 the water sewers, and secondly, as a vehicle for
14 spreading localized contamination in the field or
15 packinghouse.

16 In addition, and this is one of the factors
17 that makes recommendations in the field environment
18 particularly difficult, it's important to note that
19 if the pathogen on produce, once the contamination
20 occurs, survives until harvest and it's not
21 eliminated by any of the post-harvest handling
22 practices such as washing, such that it survives
23 until it reaches the consumer, then it can cause
24 foodborne illness. The tricky part is how long can
25 pathogens survive in that kind of environment?

1 Many pathogens may die off in the field within a
2 number of days, so the pathogen survival factor
3 needs to be overlaid with a lot of other factors
4 that we'll get into in a minute. These slides just
5 show some of the pathogens that may be carried by
6 water.

7 The other important thing to remember is that
8 even small amounts of pathogens can cause illness.
9 No one knows for sure what proportion of
10 contamination of produce originates on the farm or
11 in the packinghouse environment, and on top of that
12 many neighbors share a common watershed. Operators
13 may have limited control over some of the factors
14 that impact on water quality outside of their own
15 boundaries.

16 What we are doing is we are urging growers and
17 packers to assess their own situation and put in
18 place appropriate good agricultural or good
19 manufacturing practices in those areas over which
20 they have some control. Water quality needs vary
21 with when and how the water is used, as the degree
22 of contact between water and the animal portion of
23 the crop increases, so does the need for high
24 quality water. For example, some crops use
25 overhead spray irrigation, other crops use drip

1 action levels to tell growers when the quality of
2 water has reached a point where it should not be
3 used on the crop.

4 One of the areas in the working draft document
5 that we got a lot of comments on was when we had
6 recommended that growers perform microbial testing
7 of their water. Comments were concerned about what
8 microbe to test for, what to do, what the levels
9 that would require them to take action would be.
10 State officials that we were working with were
11 concerned about what to do or what to recommend to
12 people. We have pulled back in this document from
13 the recommendation that agricultural water be
14 tested for microbes on the basis that at this point
15 in time we don't have action levels.

16 One of the things that I noticed on site
17 visits in Florida about a week or two ago was that
18 the agricultural water uses are very different for
19 different kinds of crops. For some crops you may
20 have irrigation one time during planting or plant
21 establishment, and then no scheduled irrigation for
22 the rest of the growing season. For some other
23 crops we saw situations where irrigation proceeded
24 right up until a day or two before harvest on a
25 regular basis.

1 What we have done in the guidance document now
2 is shifted our attention from suggesting microbial
3 testing when we didn't have any further solid
4 advice to offer, to the recommendation that people
5 take a good hard look at their situation and at
6 their water sources and put in place practices to
7 ensure and maintain water quality, and I'll
8 introduce some of those practices in a minute, and
9 then also refer people to local experts that would
10 be more familiar with their individual operation
11 and the water situation in their particular region.

12 This slide shows some of the diverse water
13 sources that may be available in an agricultural
14 situation. Some growers have options as to what
15 source of water they can use. When the options are
16 available they may decide to use one source of
17 water closer to harvest as compared to another
18 source. In other situations people have a single
19 source of water and they have fewer options.

20 In general, ground water such as deep wells
21 and municipal supplies is less likely to be exposed
22 to high level of pathogens compared to surface
23 water. Now, this doesn't mean that ground water
24 sources such as canal irrigation should not be
25 used, rather it means that growers using surface

1 water may need to look harder at the good
2 agricultural practice to protect and maintain that
3 water quality. Some of the recommendations that we
4 make in this regard include things like being aware
5 of current and historical land use and potential
6 sources of contamination for your water source.
7 On-farm sources of contamination may include things
8 like runoff from leaking or overflowing manure
9 storage lagoon or allowing livestock access to
10 surface waters or pump areas. Growers should
11 follow the good agricultural practice
12 recommendations in the guide to reduce or eliminate
13 any obvious sources of contamination.

14 Soil conservation practices such as sod
15 waterways and diversion berms may also help protect
16 water sources. Are there any questions on
17 agricultural water before we move on to processing
18 water? I see one in the back.

19 MR. MATTHEWS: When you talk about testing,
20 are you saying that you all are taking back the
21 testing section within the water? I didn't quite
22 understand that.

23 MS. SMITH: What we did in the working draft
24 is we looked at a lot of industry guidance
25 documents and we relied heavily on those industry

1 guidance documents. There was a diversity of
2 recommendations in those documents. Some of them
3 had simply stated that operators should perform
4 microbial tests on their agricultural waters, and
5 we put those recommendations in the working draft
6 that we put out in November of last year.

7 One of the things that we wanted to accomplish
8 by putting that first draft out was to get feedback
9 on the effectiveness and the practicality of the
10 kind of recommendations that we were considering.
11 The feedback that we got, not just from growers but
12 also from other public health officials and
13 technical experts within FDA and USDA, was that
14 it's difficult to make that kind of recommendation
15 when you don't yet have information on telling
16 people what to do with the results of those tests.

17 In fact, at this point in time we don't even
18 have solid recommendations for what you should test
19 for. So what we have done, and one more thing I'll
20 say, is that working with the National Advisory
21 Committee for Microbiological Criteria for Food
22 that best that that kind of test -- the best
23 information you could get at this point in time is
24 maybe yes, maybe no. That that information would
25 not be definitive as to your water quality. It

1 might tell you that your water might be okay, it
2 might tell you that your water might be curable,
3 but it's most likely to tell you that you really
4 don't know for sure.

5 Another problem is that with flowing water
6 sources you could take a test at 10:00 in the
7 morning and you could sample again at lunchtime and
8 your water quality has changed because of some
9 passing event upstream. So we have not eliminated
10 the recommendations that growers test for pathogens
11 in their agricultural water, but we think based on
12 the lack of information specific to microbial
13 testing, that it would be a lot more effective to
14 shift your focus toward having people look at their
15 situation and look for potential sources of
16 contamination and either contain, reduce or
17 completely eliminate those sources. In which case
18 they've taken action that can have a long range
19 benefit and that's where we rest right now.

20 We request that people with questions go to
21 the microphone and please identify yourselves.
22 This transcript will become part of public record
23 for anyone who wasn't able to attend here today and
24 also for the use of those of us who are trying to
25 take this document to the next step, we'll have

1 your comments in writing. On top of that Camille
2 has cards in the back if one would like to write
3 down their question instead of give them. There's
4 a gentleman here who had his hand up.

5 MR. WARREN: On the water, I'm an importer,
6 distributor of product and also get involved in the
7 protection of the crops. I can assure you back in
8 Guatemala we tested our water for microbes. Every
9 bit of out fruit is washed in chlorine, it's 100
10 percent good and safe and there's a great deal of
11 saying that we don't do this and we don't know, we
12 do. I have had my water tests at ABC Lab. It
13 costs me two to five hundred dollars a test and it
14 is being taken care of to the utmost.

15 MS. SMITH: Thank you.

16 MR. WARNER: My name is Peter Warner, I'm also
17 an importer. We did had a lot of questions on the
18 use of chlorine in this issue, and questions like
19 does chlorine --

20 MS. SMITH: Could I interrupt for just a
21 minute? This is the end specifically of the
22 agricultural water, that's the use of water in the
23 farm environment.

24 MR. WARNER: In irrigation?

25 MS. SMITH: In irrigation, for example. In

1 just a minute I'll get into what we've said about
2 post-harvest and that may be better.

3 MR. WARNER: Okay.

4 MS. PEAL: I'm going to show my ignorance, I'm
5 here again. I have a production question. Let's
6 take worst case scenario, somewhere in the world we
7 use irrigation that is horrible, it's got so much
8 pathogen in it that it's terrible, we grow the
9 product in it, and I know you are going to address
10 post-production, but you wash it with the most
11 beautiful, sterile water later. Now, is that
12 product going to be adulterated by that first
13 process even though you've instituted a wonderful
14 second process?

15 MS. SMITH: That's a good question. I think
16 this is a valid point to just mention one of the
17 other things that we've added to this version of
18 the guidance document. It's a list of principles
19 that are common to successful food safety
20 programs. The number one principle on that list is
21 that prevention is preferred over correction once
22 contamination has occurred. And so rather than
23 count on processes such as washing to get rid of
24 contamination that's present, we want people to
25 focus at every step during the growing, harvesting

1 and post-harvesting and minimize hazards all along
2 the way. I see a follow-up here.

3 MS. PEAL: Sorry. What you are saying to me
4 is --

5 MS. SMITH: You can't, and I'll get into this
6 in processing, you can't count on that wash to
7 eliminate pathogens that may be present,
8 particularly pathogens like Cyclospora are very
9 difficult to get off of produce. Not all produce
10 is amenable to wash treatments. Some of the
11 berries, for example, are very delicate and are not
12 washed. It is the responsibility of everyone who
13 is involved in food production to produce a safe
14 and wholesome product.

15 If the use of really awful irrigation water
16 contaminates the crop and that crop is not
17 subjected to a treatment to correct the problem,
18 then they have not fulfilled their requirements.

19 MS. PEAL: And I as a consumer would be
20 severely hampered in making sure that product is
21 safe no matter what type of cleaning process I use
22 because it already is pretty tough for me to get
23 rid of it.

24 MR. WARREN: I want to just explain what we
25 do. Our water comes from the mountains. We have

1 reservoirs with five million gallons of water in
2 it. We check our water in the reservoir before it
3 gets to the place and the water is good, and we
4 check it also, we take it and we send it to the lab
5 before it is treated. In addition to that we wash
6 it with chlorine. It cannot be any better. You are
7 100 percent safe.

8 MS. SMITH: Thank you again.

9 MR. MATTHEWS: Charles Matthews, Florida Fruit
10 and Vegetable Association. Michelle, we've had
11 this discussion before and I agree with your
12 sentiment that testing per se doesn't increase the
13 quality or the safety of the product. And I say
14 that primarily because our methods that we
15 currently have to detect, even detecting organisms
16 are somewhat weak, is that not true?

17 MS. SMITH: We do have difficulties in
18 detecting some microorganisms. We have
19 difficulties in detecting others when they are
20 present at low levels. The additional complication
21 is if you have, for example, a running water
22 source, then the quality of that water changes so
23 frequently that testing may not give you data that
24 is valuable.

25 Now, we have not said that testing doesn't

1 have application in some situations. In a
2 reservoir situation, for example, you've got a lot
3 more of a static water quality situation and
4 testing may be something that's very worthwhile to
5 do there or to test both the quality of well water
6 in some situations.

7 MR. MATTHEWS: I think until we can recognize
8 what is important, until we have a method that is,
9 you know, within acceptable range, maybe 90 percent
10 correct, whenever it's done, that really testing is
11 more of a -- I don't know what to say, but it's not
12 a waste of money, but yet it is applicable in
13 certain situations. But for buyers to require
14 testing before they can ship to a certain location
15 or a grower can ship is really kind of a waste of
16 money unless you are specific about what you are
17 looking for.

18 MS. SMITH: I think one of the things that
19 Charley was getting at is this is another area that
20 was expressed to us in a lot of comments. There is
21 a concern that the guidance document will become de
22 facto regulation. Even though it's a guidance
23 document at this point time, it is not binding.

24 Let me back up a little. The specific
25 recommendations in this document are not binding on

1 the government or growers. What we require is that
2 the food be safe and wholesome and that's already a
3 requirement by law. We have tried to be very
4 careful and our technical experts across Federal
5 and State agencies have helped up us look at all of
6 the recommendations in the working draft and all of
7 the comments that we received to make sure that
8 this guidance document, when it is final, contains
9 recommendations that are based on sound, generally
10 accepted science.

11 There is a real concern particularly on the
12 part of growers that their customers will look at
13 their recommendations in here and write those
14 recommendations into a contract as a requirement
15 for sale. Now, that makes us try our hardest to
16 present this document in terms of the diversity of
17 agricultural practices that are out there. We are
18 sensitive to some things that may not be applicable
19 across the board being written into a contract that
20 then becomes a requirement, one example is the
21 irrigation system.

22 Granted, if you can minimize the water to
23 produce or to the edible portion of the crop
24 contact you are minimizing the potential for
25 exposure to pathogens, but we wouldn't want buyers

1 to write into their contracts that all fruit and
2 vegetables have to be grown with drip irrigation.
3 For carrots, for example, I mean, that requirement
4 makes no sense. For a lot of other type of produce
5 such as citrus growing in trees you may have an
6 irrigation system that's not drip irrigation, but
7 you may still have little or no contact with the
8 edible portion of the crop.

9 So one of the other things is at this point in
10 time microbial testing of agricultural water may
11 have usefulness in some situations, but I don't
12 think that we know enough to put a strong
13 recommendation that every one across the board
14 perform those kind of tests. There are a number of
15 things going on that may help us get closer to
16 being able to provide those kinds of
17 recommendations, but we are not there yet.

18 MR. PYBAS: Don Pybas, County Extension
19 Director. One of the issues that we are dealing
20 with locally, I know this is not a local issue as
21 far as the overall program, is one of allocation of
22 water to agriculture urban and environmental uses
23 with the Everglades restoration. At some point in
24 time there will probably be more stringent
25 guidelines and restrictions on water used for

1 agriculture. The country currently puts to sea
2 about three hundred million gallons of water a day
3 through sewer treatment facilities and ocean
4 outfalls. They, several years ago, had a
5 visibility study looking at gray water reuse in the
6 area, and at some point in time one of the
7 alternative users of that would be agriculture.
8 Has the agencies looked at the area of gray water
9 use and the implications of that as it relates to
10 these guidelines?

11 MS. SMITH: We haven't specifically focused on
12 that in the manure section of the document. We
13 looked a little bit at use of biosolids, but as far
14 as gray water or municipal waste water use on
15 agricultural land, we haven't specifically looked
16 into that in any great detail. On the other hand,
17 I attended a recent meeting that USDA Agricultural
18 Research Service held and one of the scientists at
19 that meeting just made a comment in a sidebar
20 conversation that she would have actually less
21 concern about produce grown in an area that's using
22 the gray water, because there has been so much
23 research done on water the microbial criteria are
24 in that particular situation, but it's not
25 something that we've looked into specifically for

1 this.

2 MR. WARREN: You have to forgive me. Water is
3 critical. Without water we cannot grow anything.
4 The water with the growers is critical, too. They
5 are expanding, they are growing and they have to
6 take care of it. I have been involved with the
7 crops in Central America for twenty years. I
8 myself have brought in -- right now we are bringing
9 over four million packages a year, and in the 20
10 years let's say that I brought in 50 million
11 packages or more, never once has the ever been a
12 problem with our product, with any contamination or
13 any problem. A slight problem comes up somewhere
14 and they blow it all out of proportion. Can I
15 assure that this problem that you have in the
16 water, they are very conscious of it, our people,
17 and they are doing everything they can to make it
18 as good as it can, and that's what this is all
19 about. I can assure you that they are doing it.

20 MS. SMITH: Thank you. We are aware of a
21 number of programs that are taking really
22 significant steps toward doing everything that they
23 can, in fact, covering all bases. I'd like to move
24 on to processing water, so that we can get through
25 all these sections. At the end if you think of any

1 additional questions, we can always go back a
2 little bit.

3 In the processing water section, which would
4 be a kinds of operations performed post-harvest,
5 we've again said that water quality should be
6 compatible with its intended use. Some of the same
7 things repeat itself in this section such as the
8 degree of water-to-produce contact increases so
9 does the need for high quality water. Treatments
10 toward the end of processing, as you are getting
11 closer to the consumer, particularly need a higher
12 quality water than possibly treatments at the
13 beginning of the process.

14 Now, when I say that I don't mean that water
15 used early on for dump tanks or for fluming
16 operations that it's okay if that water contains
17 high levels of pathogens at that point because we
18 are going to wash later, that's not what I mean.
19 But in some operations there are practices such as
20 recycling water. There may be a clean water final
21 rinse of the product right before packaging, that
22 water could be recycled in earlier operations. It
23 would still have to be adequate for the intended
24 use of those earlier operations, but when you are
25 bringing in produce from the field it may have a

1 lot of field soil attached. The moment that
2 truckload of produce is dumped into that water you
3 now have something that is certainly not potable
4 water anymore.

5 We said throughout this section of the guide
6 the water has to be safe and sanitary for its
7 intended use. We do not have a legal definition of
8 safe and sanitary, but we are saying that in
9 general water that meets the microbial standards
10 for drinking water would be considered safe and
11 sanitary. Although water quality needs may vary
12 for different unit operations within a process, in
13 no instance should contact with water leave that
14 produce in worse shape than it started. Some of
15 the good manufacturing practices that we recommend
16 with respect to processing water do include
17 periodic microbial testing.

18 You are now in a situation where you have more
19 control over your water source, whether it's from a
20 deep well or a municipal supply, and microbial
21 testing does have value. You have the microbial
22 criteria for drinking water as a guide. We
23 recommend if you are using antimicrobials, which
24 I'll get into in a minute, that you take steps such
25 as monitoring the pH and the levels of

1 antimicrobial chemicals that are present. As
2 produce is sent through operations, plant material,
3 field soil, other debris, may collect in your water
4 systems and the water should be changed or overflow
5 should be added as needed to maintain the water of
6 adequate quality for those particular uses.

7 Also, to maintain water quality you should
8 routinely clean all of the surfaces that the water
9 comes in contact with. Any equipment that you have
10 in place to help ensure water quality such as
11 filtration systems or chlorine injectors, backflow
12 devices should be checked on a routine basis and
13 maintained as necessary. The best type of program
14 really is not worth much unless you can ensure that
15 all aspects are functioning properly.

16 As I said a couple of minutes ago, the section
17 on principles in the beginning of the guidance
18 document stresses that prevention is preferred over
19 corrective action once contamination occurs.
20 However, produce is grown in pretty much a wild
21 environment. Even if you have followed all the
22 good agricultural practices that we are now aware
23 of, it is not possible to completely eliminate the
24 potential for any pathogenic contamination on
25 produce, because the fresh produce, which is the

1 subject of this document, is not going to receive a
2 lethal treatment such as heat treatment.

3 Before it goes to the consumer there may be
4 advantages of adding additional controlled
5 processes to your post-harvest handling. One of
6 these processes involves the use of sanitizers or
7 antimicrobials in your processing water. This has
8 the advantage of reducing pathogens on the surface
9 of the produce and it may also reduce the potential
10 of the buildup of pathogens in the processing
11 water.

12 In the guide we've said that if you are using
13 antimicrobials there are a number of things to
14 consider. First of all, you need to follow all
15 applicable FDA and EPA requirements. This is
16 probably a good point for me to pause and say that
17 throughout this guidance document we have cited
18 relevant United States Federal Regulations in those
19 areas that growers and packers need to be aware of.
20 This is also a document that we want to have global
21 significance. We want to be able to impact on the
22 safety of produce consumed by U.S. consumers
23 regardless of whether it's grown domestically or
24 internationally. One of the questions that myself
25 and Joy Salsman, Dr. Salsman is one of the other

1 drafters of this document, have asked and I'll
2 share with you here, is how to best address two
3 issues.

4 First of all, there are regulations that
5 people need to be aware of how best to help the
6 users of this document and the documents that
7 follow from it, get access to these regulations.
8 In some instances the regulations may be short
9 enough to attach as an appendage. In other
10 situations, for example in a minute we'll talk
11 about EPA Part 503 Rule, which is a book, it's just
12 not practical to put that on there. What would be
13 the most user friendly way to better help users of
14 this guide get access to the appropriate
15 regulations?

16 The other question is how best to maybe reword
17 the sections of the document where we cite U.S.
18 Regulations to let people know if they are in a
19 foreign country that if they are not following the
20 U.S. Regulations, if they are subject to their own
21 national regulations, that there need to be an
22 equivalent level of protection provided. So that's
23 my question to all of you, and if you can help me
24 on that, we'd appreciate it.

25 Getting back to the guide itself, when using

1 antimicrobials and processing water, it's important
2 to follow manufacturers' directions both for the
3 efficacy of those chemicals and also for the safety
4 of everyone handling them, and people consuming the
5 produce to which they've been applied. When
6 antimicrobial chemicals are used on produce, that
7 treatment, whether it's a wash or a dip, should be
8 followed with clean water rinse.

9 We talked a bit about maintaining the efficacy
10 of wash treatments. It's important to recognize,
11 and this goes back to a point made a little while
12 ago from the audience, antimicrobial chemical may
13 reduce but not necessarily eliminate pathogens on
14 produce. The reduction tends to be a tenth to one
15 hundredth fold reduction in the level of pathogens.

16 Furthermore, as organic material builds up in
17 this wash water, and that organic material may be
18 plant cells, plant juices, field soil, that ties up
19 the antimicrobials and their efficiency decreases.
20 Good manufacturing practices to maintain the
21 efficiency of the wash include steps such as a
22 prewash to remove as much field soil and debris as
23 possible and other steps such as adding overflow
24 water or changing water in combination with
25 monitoring the antimicrobial chemical level and

1 adding additional chemicals as needed.

2 One of the other questions that I would ask
3 the audience. In this section of the guidance
4 document we have extensive footnotes on use levels
5 for different antimicrobial chemicals, use
6 conditions. We've mentioned a number of chemicals
7 that at this point in time may not -- well,
8 definitely are not widely used on produce. They
9 may have a history of use on other types of food,
10 some of them are used by the poultry industry.
11 Research is under way right now looking at the
12 efficiency of these chemicals in different handling
13 situations and the interaction between different
14 pathogens and different crop characteristics.

15 The development team was split 50/50. We took
16 our own vote and it went right down the middle as
17 to the usefulness of these footnotes and the
18 information in them. Let us know if that
19 information is helpful to you. If it's not helpful
20 in its present form and anyone has any suggestions
21 on how to better present it, please let us know.
22 And that's the summary of the processing water
23 section, and I'm open for questions again at this
24 point.

25 MS. BOREK: My name is Tina Borek and I'm a

1 local grower. I grow vegetables. And my question
2 is going to repair your question. I know that we
3 try our best management practices in agriculture
4 and we have people come check. The Department of
5 Agriculture was in my fields a week ago and checked
6 all my records, and I can see that this grower is
7 very concerned here. I'm pleased to have you here.
8 We see you came a long way. My question is, if you
9 are importing vegetables to here, would you find a
10 problem with our inspectors going and inspecting
11 your farm?

12 MR. WARREN: We've had people inspect our
13 farms. I brought people from the lab, ABC Lab. It
14 cost me \$1,000 a day to come inspect my farm, and I
15 know, no problem, you're invited to come, too.

16 MS. BOREK: So that answers your questions on
17 whether the foreign importers would mind if you
18 went over there and use our regulations to check
19 them, and they wouldn't.

20 MR. WARREN: I think what you say is most
21 important because, people do not understand that
22 they hear these stories, they are not true. You
23 have an open door. You are welcome to come in
24 there, but all I want to say in twenty years with
25 millions of boxes of fruits there's never been a

1 problem. This thing is exaggerated all out of
2 proportion. And everybody is doing their best to
3 solve this problem which you are all bringing out,
4 that's what I want bring out. And in no way should
5 you condemn the industry that's bringing in
6 products when you don't have for all winter
7 months. This propaganda is wrong about Guatemala.

8 I have a friend that will not buy my melons
9 because they come from Guatemala because of some
10 story, how ridiculous can it be? How would you
11 feel? It's wrong.

12 MS. BOREK: It's a global market and it's all
13 we are looking for, a fairness globally. Everybody
14 needs the same treatment.

15 MR. WARREN: I ship to England and they are
16 really fussy there, more than anybody, and it's
17 clear. But I'm just saying that this is out of
18 proportion on what people are bringing in to our
19 cities, totally out of proportion. The incident is
20 microscopical and they make a mountain out of it,
21 that's what bothers me.

22 MS. SMITH: I wanted to make just a little
23 point. Lloyd said something this morning that I
24 thought was very valuable. This is a public health
25 issue, it's not a trade issue, and I don't -- I

1 just want people to be reassured from that
2 standpoint. Your invitation to come visit is a
3 good reassurance.

4 This produce safety initiative and guidance
5 document is just part of the larger Food Safety
6 Initiative. We are not singling out produce, we
7 are just looking at one area that has recently been
8 brought to our attention, the incidents of
9 foodborne illness linked to produce is very small
10 compared to other foods and the health benefits of
11 increased consumption of fruit and vegetables far
12 outweigh the risk, and so we don't in any way want
13 to discourage the consumption of fresh fruit and
14 vegetables. We just want to do what we can in this
15 exercise to minimize those potential hazards that
16 do exist.

17 MS. MEJIDES: My name is Ivonne Mejides and
18 I'm an organic farmer. I've got to see the
19 national senator hearing on Saturday on this food
20 safety. On various occasions beginning with
21 Senator John Glenn, he said that we have no winter
22 growing area in the United States. Further down on
23 the hearing we were said that we have a very short
24 growing season in the United States and toward the
25 end of the meeting they said most Americans will

1 buy American, but we cannot grow it all and
2 California cannot do it all. What about us here in
3 this area that are able to grow all this, whether
4 it be organically or commercially? Why wasn't a
5 representative of the State of Florida of
6 agriculture there trying to defend the fact that
7 what samples they had, everything on that table
8 could have been grown here locally. The only
9 senator there was the senator from Hawaii.

10 MS. SMITH: I can't address that meeting, I
11 wasn't there and I didn't see the guest list. We
12 did have comments this morning that very clearly
13 showed a significant amount of the domestic produce
14 that's consumed in the winter months comes from
15 this area even and --

16 MS. MEJIDES: I do have the list, and I
17 apologize I was at the meeting of soil and water
18 conservation, but it was very upsetting to me to
19 see people in Washington not even aware of the fact
20 that we are here and we do supply the nation with
21 winter growing vegetables.

22 MS. SMITH: We can take your comments back as
23 a part of this public record. You might even want
24 to address that committee directly.

25 MS. MEJIDES: Thank you so much, appreciate it

1 for your time.

2 MS. NIELLA-BROWN: Would you like to have a
3 break?

4 MS. SMITH: Would people like to take a break
5 before we move on to manure or should we keep on
6 rolling here?

7 MR. WARREN: One other comment, we do not use
8 any manure.

9 MS. SMITH: I think we have a vote to
10 continue, at least through the manure section, then
11 I think we may take a short break.

12 We just had a comment from the audience
13 stating very proudly that he doesn't use manure.
14 I'm not here to discourage the use of manure.
15 Manure and biosolids can both be very beneficial
16 fertilizers and soil amendments, but they do
17 represent a significant potential source of hazard,
18 some of the human pathogens are listed on this
19 slide. So when manure is used in an agricultural
20 situation certain good agricultural practices do
21 need to be followed to minimize the hazard.

22 Now, we also mentioned the use of biosolids in
23 the guide very briefly. EPA has a number of
24 regulations dealing with the use of biosolids.
25 These regulations include the requirement that

1 pathogens either be eliminated or significantly
2 reduced in conjunction with certain limitations on
3 use. These limitations include restrictions such
4 as a fairly significant amount of time between
5 applications to land and the harvest of edible
6 crops.

7 Now, as I had said, the use of manure and the
8 production of fresh produce must be closely managed
9 to limit the potential for pathogen contamination.
10 Good agricultural practices for handling manure
11 include treatments to reduce pathogen levels in the
12 manure and maximize the time between manure
13 application to crop fields and harvest of crops.
14 Growers also need to be alert of the presence of
15 fecal matter that may be unwittingly introduced
16 into the produce growing and handling environment.
17 Potential sources of contamination include things
18 such as using untreated or improperly treated
19 manure, nearby manure storage or treatment areas,
20 livestock or poultry operations and also high
21 concentrations of wildlife.

22 Treatments to reduce pathogens in manure can
23 be divided into two general categories, the first
24 category is passive. Passive treatments rely
25 primarily on the passage of time and environmental

1 factors such as fluctuating temperature and
2 moisture condition, ultraviolet irradiation.
3 Active treatments include pasteurization, heat
4 drying, anaerobic digestion, alkali stabilization
5 and aerobic digestion or a combination of the
6 above. Composting is a fairly common practice.
7 It's a controlled and monitored practice as opposed
8 to passive treatments.

9 The high temperature generated during
10 composting can kill most pathogens in a number of
11 days, therefore the risk of pathogenic
12 contamination from manure that has gone through a
13 composting treatment is reduced compared to
14 untreated manure. However, some pathogens have
15 higher thresholds, thermal thresholds than others
16 and there are enough regional differences and
17 differences in the materials that we don't at this
18 point in time have specific time temperature
19 recommendations for a composting process to
20 effectively eliminate pathogens. We also have a
21 number of questions about to what extent can
22 pathogens that survive treatments such as
23 composting regrow if the composted manure is stored
24 before use.

25 Some of the GAPS relative to handling and

1 application of manure include things such as
2 storing manure or having treatment sites located to
3 fresh produce, located close to fresh produce
4 fields may increase your risk. Grower should
5 follow the GAPs such as the secure manure storage
6 and treatment areas establishing runoff controls to
7 minimize contamination. They may want to consider
8 doing things such as covering the compost piles.
9 Some of our state folks in Michigan provided
10 recommendations for material that could effectively
11 cover manure storage or treatment areas. In some
12 places manure may be stored under a roof just to
13 minimize the amount of leachate from that stored
14 manure due to rainfall and runoff.

15 Use of untreated or raw manure carries a
16 greater risk of contamination compared to the use
17 of manure that's been treated to reduce pathogens.
18 In our guidance document we are saying that the
19 application of raw manure to produce fields during
20 the growing season is not recommended. Many people
21 who also tell you that applying raw manure to a
22 growing crop may burn the crops, and so no sane
23 person would do it anyway. Growers again may
24 reduce the risk of pathogenic contamination by
25 maximizing the amount of time between application

1 of manure and harvest of crops. This is one of the
2 areas where we received a significant number of
3 comments on the working draft.

4 In the working draft document we cite the
5 National Organic Standard Board recommendations for
6 a minimum of 60 days between manure application and
7 harvest, and we also cited 120 days, which was
8 provided to us, information provided to us in
9 antidotic stories. Comments came in and the
10 comments are correct that we do not know how long
11 pathogens can survive in the field and we don't
12 know how long that would be under different
13 conditions.

14 We have kept in the proposed guide the
15 reference to the National Organic Standard Board's
16 60 day minimum. We have deleted our specific 120
17 day reference. We have cited some research that
18 may indicate that at least under some situations,
19 some pathogens can survive significantly longer but
20 we have stated that at this point in time no one
21 knows how long pathogens can survive. Because
22 composting and treatment such as composting may
23 reduce, but not eliminate pathogens, we also
24 recommend in the guide that growers consider some
25 of the practices that we've recommended for use of

1 raw manure, even when they are using composted
2 manure. Practices such as maximizing the time
3 between application and harvest.

4 There's a lot we don't know at this point
5 about pathogens in manure. Research is largely
6 just starting in this area. Much of the research
7 that is the basis for current, they call them best,
8 management practices for manure handling based on
9 other factors such as soil, fertility and crop
10 needs. So it's just now that we are starting to
11 look at the food safety issues. As additional
12 information becomes available we hope to further
13 refine those recommendations. That's the end of
14 the manure section. I'm open for comments.

15 MS. PEAL: Sorry. Science question again, and
16 I know you've indicated that this is new avocation
17 for you in terms of manure, and its application and
18 all, but on one of your supposition, based on the
19 fact that possibly using let's say for example
20 E-Coli latent manure, it's there, you know it's
21 there. Can that get into the body of the product
22 as opposed to getting it on the outside, which you
23 know can happen, which could be washed out or can
24 be raised into it. I mean, can it be present, can
25 that pathogen through the growing process be

1 present and never be removed by the washing process
2 by virtue of the fact that it was grown into it and
3 is there at all times?

4 MS. SMITH: I think by far the largest concern
5 is pathogens that are present on the surface of
6 produce when the produce is harvested. I don't
7 personally know of any instances of pathogens
8 uptaking the produce. I'm not saying it's not
9 impossible, but the largest concern is what's on
10 the surface.

11 There are some situations such as cutting
12 where it may be introduced. The guidance document
13 does cover products like fresh cut, but it also
14 states that additional considerations may be
15 necessary because of the added processing steps
16 that follow, and we didn't address them
17 specifically at this point in time. Now, I think
18 there was another part to your question that I'm
19 missing or slipped my mind.

20 MR. GOMEZ: Michelle, I think you may deal
21 with some of that as well when you -- with wash
22 waters and so on, because there's certain produce
23 that can internalize.

24 MS. SMITH: We didn't get into that when -- I
25 skipped over that in processing water, but another

1 phenomenon that has been noted by researchers is if
2 there is E-Coli in processing or if there is
3 pathogen in general in processing water. With a
4 product like tomato that has an internal air space,
5 if that product is exposed to colder water it can
6 adjust the pressure differential, sucks the water
7 into the produce and if pathogens are present sucks
8 that is in also.

9 Now, in the working draft we made the
10 recommendation that water temperature be ten
11 degrees warmer than produce and that it be
12 chlorinated. Many of the comments that we got said
13 that that was not a practical recommendation. The
14 primary consideration for most crops is removing
15 field heat. It's not a hazard for most crops.

16 At this point in time the only crop that we
17 have solid research that does that is tomato. On
18 our recent site visits we found that tomato packers
19 were carefully monitoring water temperature and
20 making sure that they were ten degrees warmer.
21 Now, the tomato packers they have been doing that
22 for some time because they've also noticed that
23 water uptake phenomenon. And if you get water
24 sucked into your tomatoes and they spoil, they are
25 not marketable product.

1 MR. GOMEZ: Let me interrupt again. There's
2 also solid evidence in peppers and apples pathogens
3 can be internalized, and we've all seen-- I think
4 we've all seen mold growing inside of peppers and
5 so on all those internalization, but basically the
6 peppers and apples are all things --

7 MS. PEAL: Thank you, sir. Once again, I'm
8 just trying to portray that so many cases we've
9 heard that the consumer has the utmost
10 responsibility of making sure these are taken care
11 of, but these are things that I could not as a
12 consumer control. I would not know that they were
13 in there and there's nothing I can do to make it
14 safe once it gets to me. Am I correct in that
15 assumption, just on the examples that we just
16 talked about in uptake -- there's nothing I can do
17 to make it safe for myself if this, in fact,
18 transpired?

19 MS. SMITH: I hate to ever tell anyone there's
20 nothing they can do. I think that there are a lot
21 other things consumers can do in general just as
22 far as washing produce, safe handling. We are all
23 partners in this throughout the chain, so there are
24 earlier responsibilities before produce gets to the
25 consumer. Specifically what you could do with that

1 tomato, I would have to talk with our
2 microbiologists and see.

3 MS. PEAL: But given there are situations that
4 I as a consumer would not be able to control unless
5 I was also a scientist in my kitchen. You are
6 agreeing with me on that one prong?

7 MS. SMITH: Well, I'm thinking that as a
8 consumer you look at your relative risks, you look
9 at your health benefits. We want people to have
10 confidence in the food supply. The situation that
11 you are describing of --

12 MS. PEAL: It's possible.

13 MS. SMITH: It's possible, it is very
14 unlikely.

15 MR. WARREN: I just want to make one comment.
16 Maybe about two years ago they found some
17 cantaloupes that had a problem in it and where do
18 you think it came from? Some damn fool put it in a
19 truck that was hauling animals with waste and put
20 the cantaloupes in the waste, one incident. Since
21 then they've never found it at all.

22 Now, everything -- you know, nature has it's
23 way. You grow a pepper, it's perishable. It
24 rains, it does this and that, so far, so you can't
25 control -- the air you breath is contaminated,

1 should we stop breathing. So let's be sensible
2 about this thing. Our product is safe and it's
3 good and this propaganda should not be against us.

4 MS. SMITH: I think on that note I'll give us
5 all a seven minute break. We can come back here at
6 3:30.

7 (Thereupon a recess was taken in the
8 proceedings, after which the proceedings
9 continued as follows:)

10 MS. SMITH: I think we are about ready to
11 start the next section on sanitation and hygiene.
12 One of the things about this guidance document is,
13 its first purpose is to increase the level of
14 awareness of areas that may be a potential source
15 of contamination, and then it goes from there to
16 make recommendations for specific practices that
17 might be followed to reduce or minimize the
18 hazards.

19 We need to recognize that there's a diverse
20 agricultural work force in the U.S. and globally
21 made up of individuals from different backgrounds
22 and cultures. It cannot be assumed that this work
23 force knows about or follows good hygienic
24 practices while working with fresh produce. The
25 guide recommends that all operators establish good

1 hygienic practices that should be followed by
2 everyone who works with or handles fresh produce.
3 Everyone at all steps of the food chain who handles
4 food is a food handler. Perhaps it is the first
5 step in establishing good hygienic practices for
6 growers and packers to be aware of existing State
7 and Federal regulations regarding standards for
8 worker hygiene and sanitation in the agricultural
9 and produce packing operations.

10 For example, the Occupational Safety and
11 Health Act has set a standard for protecting
12 worker's health in the field and in packing
13 facilities. It's important to remember that
14 infected employees increases the risk of
15 transmitting foodborne illness. Therefore, all
16 personnel should comply with the established
17 hygienic practices.

18 What can growers and packers do? We recommend
19 that they establish a training program to teach
20 good hygienic practices. Each program should be
21 geared toward the level of understanding of the
22 worker of formalized program along with periodic
23 evaluation and follow-up training sessions has
24 proven to be effective in other segments of the
25 food industry.

1 Operators with the person in charge of the
2 employees should also become familiar with typical
3 signs and symptoms of infectious disease. Workers
4 with diarrheal disease and other signs of
5 infectious disease should not work with pressure
6 produce or produce handling equipment. Lesions
7 containing pus that are located on parts of the
8 body that might have contact with fresh produce can
9 contaminate it. Operators should provide protection
10 for those workers such as gloves or waterproof
11 bandages. If a lesion cannot be adequately covered
12 so it will not have contact with produce, the
13 worker should not be handling fresh produce. The
14 guide also mentioned the use of gloves. In
15 comments to our working draft this was another area
16 that generated an awful lot of comments. In the
17 working draft we had said that all workers and
18 visitors to farms and packing houses including
19 inspectors should wear gloves. Comments that we
20 received in return noted that the gloves themselves
21 can be a source of contamination. They also noted
22 that some crops have their own particular needs as
23 far as glove use goes. Some crops, for example,
24 need to be handled using cloth gloves. What we
25 have done now in the proposed guide is take a step

1 back from the recommendation that gloves be worn by
2 all people, we're stating now that gloves may be a
3 good hygienic practice in some situations in
4 combination with appropriate hand washing
5 practices, that all people that handle produce
6 should follow appropriate sanitary and hygienic
7 practices making it more of a performance based
8 recommendation, and that in no instance should
9 gloves serve as a vehicle for contamination.

10 Part of the training program as I had
11 mentioned a minute ago would include just teaching
12 the principles of good hygiene. Don't assume that
13 everyone knows the correct way to wash their hands.
14 With respect to toilet facilities, the guide
15 recommends that workers be encouraged to use
16 available facilities. This is particularly
17 important that the facilities be accessible and in
18 good condition so that people will be likely to use
19 them as opposed to undesirable practices like
20 relieving themselves in the field. Ensure that
21 employees have an opportunity to use the facilities
22 whenever they are needed, not just on scheduled
23 break times.

24 Many of the requirements for facilities are
25 set in OSHA regulations, which are cited in this

1 guidance document. In this area and throughout the
2 guidance document we have stated that the
3 recommendations in the guide are not meant to
4 replace existing State or Federal regulations.

5 Toilet facilities and handwashing stations
6 should be accessible, properly located, well
7 supplied with toilet paper, a wash basin, water,
8 soap, sanitary hand drying devices and a waste
9 container. All facilities should be kept clean and
10 sanitary and container used to store water for hand
11 washing should be clean and sanitized on a routine
12 basis and refilled with potable water.

13 When handling sewage disposal from sanitary
14 facilities, operators should follow all applicable
15 EPA regulations. Tank trucks should have direct
16 access to toilet for servicing and there should be
17 a plan in place for containment of any waste that
18 may leak or spill from, for example, portable
19 toilet facilities to ensure that this material does
20 not contaminate growing produce.

21 A number of comments were concerned about
22 recommendations in the guide to follow sanitary
23 practices in the field. Some of these comments
24 brought up the point that the field is not a
25 sterile environment and they expressed concerns

1 that the guide was trying to make a field into kind
2 of a sterile operating theatre situation, and
3 that's certainly not what we expect to do with the
4 natural field environment. However, there are a
5 number of practice that growers can follow. These
6 practices include things such as cleaning, harvest
7 storage facility prior to use, repairing or
8 discarding damaged cartons, cleaning muddy
9 containers before use to help prevent
10 cross-contamination from one load of produce to
11 another or from materials that may have come in
12 contact with containers when they were stored
13 between harvest seasons. Other recommendations
14 include removing as much mud and dirt from produce
15 as practicable in the field and ensuring that
16 produce that is packaged in the field is not
17 exposed to any sources of contamination in that
18 process.

19 Equipment should be use appropriately. Now,
20 equipment here is a very broad category. It
21 includes not only trucks and other vehicles, but
22 the bins and buckets used for the harvesting and
23 transport operation, table packaging material
24 etcetera. Any equipment used to haul or carry
25 garbage, manure or Paul's goats, should be

1 carefully cleaned and disinfected before it's used
2 to transport or carry fresh produce. The guide
3 recommends that operators assign someone to be in
4 charge of equipment and be responsible for ensuring
5 it's maintained in an appropriate condition and
6 kept as clean as possible.

7 For all packing facilities, packinghouses and
8 the grounds around them, a general recommendation
9 is that they be maintained in good condition to
10 reduce the potential for microbial contamination of
11 fresh produce. As I had mentioned before some of
12 the controls that you can use in the packing
13 facility is to remove as much dirt and mud as
14 possible from the produce while it's still out in
15 the field. Depending on the situation you may have
16 varying abilities to do them. In our recent site
17 visits we saw a carrot operation where it seemed
18 like the trucks were unloading at least as much
19 field soil as they were carrots. Now, this
20 operation was making every effort in their other
21 practices to follow good manufacturing, good
22 agricultural practices and I don't want to say that
23 it was a bad operation, but the fact that they were
24 bringing in so much field soil placed a tremendous
25 burden on their subsequent cleaning steps, and if

1 there was something that they could have done such
2 as even adjusting their harvest equipment to leave
3 more of that soil in the field and bring less of it
4 into the packinghouse environment that would be
5 desirable. On top of that the conditions were very
6 dry, the field soil that they were bringing in was
7 blowing throughout the packinghouse even as high as
8 the second story catwalks, so it was something that
9 in that situation it would be worth them looking at
10 further.

11 All equipment in the packing facility that
12 comes in contact with the produce should be as
13 clean as possible, kept in good working order. All
14 packing areas should be cleaned at the end of each
15 day of use or more frequently as needed.

16 If produce is cooled, the cooling system
17 should be maintained in proper working order and
18 kept clean. Some of the antidotal stories that we
19 picked up from the State public health officials
20 that helped us with the comment review dealt with
21 is hydrocoolants for water was changed once a year.
22 Now, when situations like that come to your
23 attention that is not the industry norm, but it's
24 certainly something that if the level of awareness
25 for that particular operation can be raised and

1 that practice changed, we're taking steps in the
2 direction that we want to go in. It's also
3 important in the facility to clean all product
4 storage areas on a regular basis, removing dirt,
5 debris and product waste.

6 All packing facilities should establish a pest
7 control system. They should maintain the grounds
8 in good condition, including appropriate waste
9 storage areas and frequent waste removal. Monitor
10 and maintain facilities regularly to ensure that
11 the pest control program is effective. Block
12 access of pests into enclosed facilities. Some
13 packinghouse operations may even be a rolling
14 conveyor belt going down the field or they may be a
15 pavilion style structure to the extent possible,
16 and some of those it's very difficult to control
17 what may fly by or run by as you are going down the
18 field. But in an enclosed facility it's very
19 important to exclude pests from that facility. Use
20 of a pest control log may also be helpful in being
21 able to assess your own particular operation and
22 how it's going, what's been done, what may need to
23 be done.

24 A new section in the proposed guide deals with
25 customer pick operations. This is in response to

1 some of the comments that we got on the working
2 draft. We are urging operators who permit
3 customers to come into their fields and pick
4 produce, to encourage those customers or take
5 advantage of this opportunity to encourage the
6 customers to use good handling practices for fresh
7 produce. Customers should follow a establish
8 hygienic practices and all customers who pick
9 produce should be provided with properly equipped
10 hand washing stations in the field and there should
11 be clean, well supplied and convenient restrooms
12 for their use. Finally, we encourage operators to
13 educate consumers about washing fresh produce that
14 is to be eaten raw.

15 In the transportation area it's important to
16 remember that produce may become contaminated
17 during loading, unloading, storage and transport
18 operations. Workers involved in loading and
19 unloading produce should follow good hygienic
20 practices, just as anyone else involved in the
21 handling of produce. We recommend that operators
22 assign someone specifically to be responsible for
23 ensuring trucks and transport cartons are clean and
24 sanitary before produce is loaded. We recommend
25 that they find out what previous loads were carried

1 in that truck before loading produce. Some of the
2 packing operations and growing operations that
3 we've seen rather than trying to inquire as to the
4 previous load of the produce may just choose to
5 clean those trucks and do that regardless of what
6 was carried before.

7 During transport, as at every other stage
8 along the way, maintaining the appropriate
9 temperature to maintain the quality of that produce
10 also helps minimize risks to produce. That is
11 sound and, in fact, provides better barriers
12 against microbial contamination compared to produce
13 that is damaged. Are there any questions on worker
14 sanitation, hygiene, facility sanitation and
15 hygiene?

16 MR. MATTHEWS: Hello again, I'm Charley
17 Matthews from Florida Fruit and Vegetable. A
18 question about the field sanitation and the packing
19 house sanitation. If you are currently following
20 OSHA field sanitation regs, do you feel like that
21 is adequate from a worker's sanitation
22 perspective?

23 MS. SMITH: Okay. I've got to say one thing
24 right up front, two of us worked on this guidance
25 document, Dr. Salsman was more the expert on this

1 section. Wayne Derstine, who's still here, has
2 volunteered to be my backup on technical questions
3 in this area because I'm not intimately
4 knowledgeable of OSHA regs. I didn't know if
5 strict adherence to those regs would ensure that
6 everything that's being done to -- that's possible
7 has been done. I can't tell you.

8 One thing I will say from my own observations
9 just assuming that the OSHA regs say that a certain
10 number of facilities has to be within a certain
11 number of feet or a certain number of employees,
12 and that's my understanding. Things should still
13 be easily accessible, common sense on the part of
14 the grower. If the requirement is 50 feet but
15 there's a big ditch in the way, it's going to take
16 somebody an extra ten minutes to climb through that
17 ditch, they may not bother to come all the way out
18 to the other side.

19 MR. MATTHEWS: From my perspective it would be
20 advantageous if the regulations and the guidance
21 were transparent so that we did one thing versus
22 having to do one set of deals for FDA and another
23 set of deals for OSHA. I mean, it makes no sense,
24 where you can, to make the two regulations
25 transparent of each other.

1 MS. SMITH: If there's any place that you are
2 aware of that we get inconsistent, let us know.

3 MR. MATTHEWS: I'm asking you. I think it's
4 consistent, that's my question.

5 MS. SMITH: Dr. Derstine.

6 MR. DERSTINE: Dr. Derstine, Florida
7 Department of Agriculture. Charley, if I
8 understand your question, do you feel that we are
9 consistent enough between the sanitation facilities
10 that we have for packinghouses, which would be
11 regulated by FDA, versus those regulations of OSHA,
12 which regulates the field employees, as I recall
13 them, is that --

14 MR. MATTHEWS: There are two different
15 standards, one is field sanitation standard and the
16 other one is facility or packinghouse standard.

17 MR. DERSTINE: Yes.

18 MR. MATTHEWS: I guess in specific to the
19 field, my question was, if you are following,
20 you're abiding by those regulations, to me it would
21 seem that those were adequately adequate for
22 workers regarding the things that FDA is talking
23 about, you know, washing hands, providing soap and
24 towels and those types of things.

25 MR. DERSTINE: They certainly appear to me

1 that they are, talking about being transparent,
2 that they are. The OSHA is not asking for
3 anything. You have to understand, because they are
4 mobile that you move them with the workers, but
5 it's the same requirement if they washed their
6 hands after using the toilet facility and that is
7 same thing that FDA asks for in a fixed facility.
8 And I don't see that there's any different
9 requirements other than sometimes the distance you
10 may have to go to, like Michele said, if there's a
11 big 20 foot ditch there and you have to walk all
12 the way around you can always just stop and do it
13 there. That's where maybe the difference that you
14 are trying to get at.

15 MR. MATTHEWS: Okay, OSHA requires that they
16 be accessible, that's not appropriate for hazard --

17 MR. DERSTINE: FDA we require in fixed
18 facilities they be accessible, so we require
19 certain things about hand washing, soap, towel
20 etcetera, I think to me they are the same.

21 MS. SMITH: I'm going to wrap up now with the
22 discussion of traceback. This was covered in great
23 detail by Doug Tolen this morning and I think he
24 did a wonderful job. I'll just introduce a little
25 bit of what the guidance documents specifically

1 does. In our working draft we got a number of
2 comments from people that were concerned about the
3 amount of paper work or the cost of instituting a
4 lot numbering system or some other system to
5 facilitate traceback, and the point that we want to
6 make in this guidance document is that although
7 traceback systems may not be able to prevent that
8 initial outbreak, they certainly would be a good
9 complement to an effective food safety program.
10 And there are a number of public health benefits
11 and economic benefits to the industry of doing
12 everything that they can to pursue effective
13 traceback systems, and we get into these a little
14 bit.

15 The point that I would like to make here is
16 that once an epidemiological study has implicated
17 or identified a food item that's suspected to be
18 the source of the foodborne outbreak, there are two
19 ways to trace it back to its source. One of the
20 ways is using lot numbers or other identification
21 if they are available. The other way involves
22 looking at the records at the point of services or
23 point of sale, interviewing a lot of employees
24 there and working your way backwards through the
25 chain talking to people at each step along the way,

1 looking at record. This takes a lot more time,
2 more resources and relying on people's memories may
3 be a less than effective system.

4 We heard a little bit this morning about
5 challenges facing the fresh produce industry with
6 respect to effective traceback. One of these
7 challenges is or two challenges are the practices
8 of reusing containers so that the identification on
9 a container may have nothing to do with the product
10 that's in it at that moment. And the practice of
11 commingling at repacking houses or at other
12 distribution points.

13 These are big challenges, we recognize. They
14 are certainly hurdles to be overcome, but the
15 benefits of an effective traceback system are
16 certainly incentive to look at ways to overcome
17 those difficulties. Some of these benefits are
18 that an effective traceback system may lead to
19 specific region packinghouse or fields rather than
20 leaving the entire commodity group open to
21 suspicion. It may limit the extent of the
22 outbreak, it may limit the population at risk to be
23 able to quickly find out the source of a product
24 that's implicated. It may also help reduce
25 consumer anxiety about consumption of a particular

1 commodity if the information could be made
2 available very quickly that the source was
3 identified and the cause was an isolated
4 occurrence.

5 Improved traceback may also be useful from a
6 public health and grower perspective in that the
7 information gained may help us refine the types of
8 good agricultural practices and good manufacturing
9 practices that we are recommending based on a
10 clearer idea of where the potential hazards
11 actually are. It was mentioned this morning and
12 I've seen myself on site visits that some industry
13 segments are currently using lot numbering systems
14 that may identify produce all the way back to even
15 the individual harvester. That was very
16 encouraging for me to see, it exceeded my
17 expectations. Any information that we can get
18 leading back, at least, to the farm level helps
19 narrow the search for a cause.

20 .And finally once good agricultural practices
21 or good manufacturing practices are adopted by
22 growers or packers, there needs to be some kind of
23 system in place to ensure that the process is
24 working correctly. Regular monitoring of the
25 operation to ensure all practices are followed is

1 one of your recommendations. I had mentioned
2 earlier that for some practices it may be very
3 worthwhile to have a certain individual who is
4 specifically assigned the responsibility for making
5 sure that employees receive appropriate training or
6 for making sure that trucks are clean and sanitary
7 before produce is loaded. Without accountability
8 the best attempt to minimize the risk of
9 contaminating fresh produce may be subject to
10 failure. And that's the wrap up of my summary of
11 the guide. If there are any questions on this last
12 section or any of the other sections, I'm open.

13 MR. WARREN: I just want to comment on the
14 things we are doing on our farm. First place the
15 sanitation situation, it can be improved.
16 Basically the toilet facilities on the farms in
17 general out there are very rudimentary on people,
18 and we are planning to put septic draining systems
19 for the thing and we are looking into having mobile
20 toilets in the field. It's a big investment. The
21 truck alone to clean up the waste is \$10,000 in the
22 mobile things, so it isn't such a simple situation.

23 Everyday our packinghouse is washed down,
24 sanitized completely, all the equipment. We have a
25 doctor on call to examine our people all the time

1 and he comes several times a week, if necessary on
2 a daily basis. We feed them lunch everyday. It
3 costs us one quetzal. One quetzal is about 15
4 cents. We work out the entire situation. So all
5 our pallets -- we ship 2,000 pallets a week, every
6 one of them electronically scanned, which tell
7 which field, when it was picked and so forth, all
8 background. All these things are being covered.

9 Now, the other people, it's going to be --
10 it's very, very difficult because the little farmer
11 can't do that. All my of people needed technical
12 training so they could perform all these
13 situations, so it's not an easy situation, but they
14 are attempting to do that.

15 Just once again, just repeating it, the
16 product coming in from all these growers, we are
17 all very concerned and they are going to do their
18 best to correct it and the people should feel
19 assured about it, because during winter months we
20 can't grow the produce here, it's cold. The
21 weather controls it. For six months we bring in
22 product so the people can have healthy products and
23 eat it, and we want to work with you and work this
24 thing out together. So this is the message I've
25 been trying to say. Thank you.

1 MS. PEAL: There's a lot of soft language in
2 the document, this concerns me as a consumer. I'm
3 not a bit concerned about the people surrounding me
4 today. As a matter of fact, I'm enriched by people
5 that are here today. You are here because you care
6 and you are here because you are going to do the
7 best for the consumers, not just the United States
8 but of the world. We are not breaking up the
9 memorial as I spoke earlier and saying, gee,
10 somebody is going to get sick from my product. You
11 are here today to keep us safe, but this is a very
12 small gathering and that's why I'm concerned that
13 we need tough language to make sure that those
14 people who aren't with us in the game will make
15 sure that the consumers will be safe. I want
16 everybody to be on my watch and I want everyone to
17 be on the FDA's watch. I want the USDA to be on
18 watch. I want every government agency, every
19 producer, every harvester, to be on watch to make
20 sure that we are all safe. We wouldn't have been
21 here today had there not been serious incidents of
22 illness and death, that's why we've had this
23 gathering. I've heard wonderful things, but I want
24 to make sure that we don't just keep it in a soft
25 sense. Let's put some real hard lining action into

1 it and then maybe the next time we'll meet it will
2 all be at a luncheon not in a room saying what can
3 we do to make it better. We'll have made it better
4 and consumers in not just the United States, but
5 the entire world will be safer because of your
6 efforts. Thank you.

7 MS. SMITH: I'd like to say one thing in
8 closing. We really are looking for your comments.
9 I appreciate all the wonderful comments that have
10 been provided here today. As has been mentioned
11 before, the comment period continues until June
12 29th for yourself and your colleagues. The final
13 guide that we publish in October can only be as
14 good as the input that you provide.

15 A lot of comments from the working draft
16 helped us bring this to where we are now. We want
17 it to be as good as it can be, and we are looking
18 for your help to do that.

19 MR. WARREN: Just one other thing, it's an
20 education process, it isn't a government process.
21 You have to reach the people that are doing it and
22 make them understand why it's important, why it's
23 good for them, that's why the challenge.

24 MS. PEAL: And that's what I'm worried about.
25 I've heard the term voluntary so much today, sir,

1 and I am a product of the voluntary process that
2 didn't work for my family.

3 MR. WARREN: You still have to be
4 understanding and knowing there's just so much that
5 we can do and do our best and not condemn the
6 situation for some isolated incident.

7 MS. PEAL: Sir, when it's your own family
8 member it's not isolated, it is entirely global.
9 And I know a lot of instances where there are
10 family members, so I'm hopefully here representing
11 that group of people who have personally suffered
12 the tragedy of maybe not all good practice being
13 put out and around in this particular arena.

14 MR. WARREN: But regardless everyone can only
15 do their best. That's what we are trying to do.

16 MS. NIELLA-BROWN: Any other formal statements
17 from the audience. Sir?

18 MR. MATTHEWS: Good afternoon. My name is
19 Charles Matthews, and I am the Assistant Director
20 with the Florida Fruit and Vegetable Association,
21 beyond that locality it's called FFVA. FFVA is a
22 55 year old voluntary grower association which
23 represents the majority of vegetable, fruit and
24 sugar cane production in the state. Florida has a
25 highly diverse produce industry that has farm gate

1 value totaling approximately \$3 billion. Florida
2 leads the nation in the production of 14 different
3 individual fruits and vegetables including citrus,
4 tomatoes, sweet corn, snap beans, and limes, to
5 name a few.

6 For several years, FFVA has been actively
7 involved in the promotion of increased consumption
8 of fruits and vegetables, as well as science-based
9 efforts to educate growers to further enhance the
10 wholesomeness of the produce grown and consumed in
11 the United States. Americans now consume about one
12 billion servings of fruit and vegetables each day.
13 These one billion daily serving provide a myriad of
14 health benefits. American farmers produce the most
15 wholesome agricultural products in the world.
16 Unfortunately, the incidents of foodborne illnesses
17 attributed to fresh produce have increased over the
18 past 10 years. I strongly feel that this increased
19 incidence is not a reflection upon the American
20 producer, but rather a combination of several
21 factors including an increased scrutiny by various
22 health organizations, the relaxation of consumer
23 safeguards such as the known continuous cold chain,
24 proper preparation, etcetera, also the
25 cross-contamination with other food items and the

1 amount of fresh fruit and vegetable imported to the
2 United States. For example, Federal statistics
3 tell us the amount of imported fruits and
4 vegetables consumed in the United States has
5 doubled in the past 10 years. These increased
6 incidences will likely continue as governmental
7 agencies continue to focus on fresh produce. As
8 this occurs, it is extremely important that
9 regulatory agencies not discredit our American
10 producers' safest produce in the world, but rather,
11 focus on true science-based factors that contribute
12 to this perceived increased incidence.

13 FFVA has been actively involved in the food
14 safety issue for over half a decade now. We have
15 been active at the national level and even at the
16 low local level in a variety of endeavors. In
17 general, our industry, our produce industry has
18 been extremely proactive on this issue. Throughout
19 these efforts we sincerely believe that most of our
20 industry has moved to where they need to be in
21 regard to food safety.

22 We appreciate that the agency's proposed guide
23 has been developed as a guidance, as opposed to
24 regulation. This is extremely important given the
25 diversity and scope of our industry. Most of our

1 farming practices and post-harvest practices are
2 the result of literally generations of farming
3 families' unique improvements toward our current
4 state of the art supremacy and wholesome and
5 inexpensive produce production. There are
6 literally hundreds and probably thousands of
7 examples of this diversity ranging from the number
8 of crops that are produced, the number of soil
9 types that we grow those crops in, different
10 irrigation practices, to different harvesting
11 procedures, packing facilities and post-harvest
12 practices. In order to encompass this diversity,
13 FDA and USDA activities must remain guidance in
14 nature.

15 FFVA is currently digesting the FDA and USDA
16 guide and we will soon be submitting formal
17 comments to the agencies. In general, I would like
18 to share with you some of our observations to date.
19 First, we sincerely appreciate the agency's
20 sensitivity to our needs and concerns. The
21 proposed guide was well written and for the most
22 part easily understandable. The guide also covers
23 the three main areas we feel are most important to
24 food safety, and that includes water, animals,
25 including humans, and equipment.

1 While we applaud the efforts of FDA and USDA
2 at the field and packing level, there does not
3 appear to be the same sort of attention that other
4 levels within the produce chain, which are linked
5 closer to human consumption. The old saying about
6 a chain is only as strong as its weakest link is
7 that applicable to our produce system where the
8 links also include transportation, as you mention,
9 distribution, retail and consumer preparation. And
10 unless efforts in these area are concurrently moved
11 forward, the strong link that we create at the
12 production level may break down as we move toward
13 the consumption link.

14 The USDA/FDA guide should remain focused on
15 strong science excluding the influence of political
16 science. Our understanding of and the science of
17 potential microbiological pathogens associated with
18 fresh produce is only in its infancy, yet, there
19 are political pressures which are driving the
20 agencies toward rapid implementation. In our haste
21 to do something we must be sure that that something
22 has a strong science and research basis. Guidance
23 based on mere observations, assumptions, and/or
24 speculations may, in fact, worsen the situation.
25 For example, we know that chlorination of tomato

1 wash water significantly reduces the potential for
2 microbial growth. Yet, transferring this practice
3 to peppers may increase the potential for microbial
4 growth. Other examples would be agency
5 observations of production practices such as the
6 use of surface irrigation water in California or
7 pesticide carrier water in Guatemala. The jump
8 from suspected practices to hazards must have a
9 scientific basis. Dramatic increases in research
10 are needed to do two things: A, determine where
11 potential hazards may occur, and B, determine which
12 practices may mitigate these potential hazards.

13 The other general area we would like to
14 address today is the distinction between fresh and
15 processing practices. There are current State and
16 Federal regulations which govern processing
17 practices for food establishments which prepare
18 foods for consumers. There need to be a crystal
19 clear distinction between these types of
20 establishments and produce grown and packaged for
21 bulk shipment at the grower level. Because our
22 crops are produced in the natural environment, they
23 cannot be expected to be 100 percent free of
24 microbiological agents. Our crops coexist with the
25 natural environment. There are numerous State and

1 Federal regulations which govern how we interface
2 with the environment, and that environment includes
3 birds, bees, bears and alligators to name a few.
4 Crops produced in the natural environment should
5 not be subject to the same regulation intended for
6 food preparations establishments.

7 In conclusion we appreciate the opportunity to
8 provide input to the guide and FFVA stands ready to
9 work with FDA and USDA state agencies on this
10 critical effort. Thank you.

11 MS. NIELLA-BROWN: Thank you for you
12 comments. Any other formal statements from the
13 audience?

14 MS. GREEN: My name is Katherine Green and I'm
15 with the Dade County Farm Bureau the Farm Bureau
16 represents local growers here in this area and
17 Homestead area. I find that it is of utmost
18 importance that if our growers are going to be
19 given these guidelines to follow that other
20 countries that we allow to import fresh produce
21 into the United States also be required to follow
22 the same guidelines on growing conditions that are
23 established here in the United States.

24 Also for your traceback segment that you
25 talked about just a few moments ago, I think that

1 it is very important that we establish a country of
2 origin labelling law, and I just would like to put
3 that on public record that here in Florida we do
4 have country of origin labelling, but we are the
5 only state here in the United States that does have
6 that requirement. And for consumers to not know
7 where their fresh produce is coming from and to not
8 know if those countries are being asked to comply
9 with the same guidelines or the same restrictions
10 that we are being asked to comply with here in the
11 United States, I think it's an injustice to the
12 consumer and I would like that to be on public
13 record, thank you.

14 MS. SMITH: Thank you.

15 MR. WARREN: Can I answer that very briefly?

16 MS. NIELLA-BROWN: Very briefly, please.

17 MR. WARREN: I'm trying to explain what we are
18 trying to do. Inspecting each country is
19 impossible, six countries that one time ship melons
20 in the United States they come from Guatemala,
21 Honduras, Costa Rica, Mexico and Nicaragua, all of
22 them, so they buy from this. And how in world are
23 you going to have these countries inspected, it's
24 impossible. And all of us are subject when it
25 comes under that inspection, it has to be right.

1 There is a lot of foolishness in this country with
2 the safe importing. That's what it is. That's
3 all.

4 MS. NIELLA-BROWN: Thank you. At this time
5 I'd like to ask any speakers that are still
6 remaining in the room to please come forward.
7 Speakers.

8 I'd like to ask you if you have any final
9 comments for the day. Michelle Smith?

10 MS. SMITH: I gave mine.

11 MS. NIELLA-BROWN: Mr. Tolen?

12 MR. TOLEN: It's late, let's go home.

13 MR. DERSTINE: I'll second that.

14 MR. CARSON: No comments.

15 MS. NIELLA-BROWN: All right. Then we'd like
16 to really thank the speakers, the audience for
17 their active participation and also we would like
18 to thank the Dade, Miami-Dade County Cooperative
19 Extension Service for hosting the meeting at their
20 facilities.

21 And one last word, if you are like me, when
22 you are driving home or flying home you are
23 thinking of several things that you should have
24 wrote up or brought up at the meeting and you did
25 not, please write them down and send your comments.

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(Thereupon the proceedings were concluded.)

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CERTIFICATE OF REPORTER

STATE OF FLORIDA

COUNTY OF DADE

I, Pearlyck Valiente, being a Shorthand Reporter, certify that I was authorized to and did stenographically report the foregoing proceedings; and that the transcript is a true record of the testimony given by the witnesses.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

Dated this 26th day of May, 1998.

Pearlyck Valiente

Certified Shorthand Reporter

